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# ATTY. DOCKET NO. APPLICATION NO. 10165-037-999 10/520,140 LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) Brines et al. FILING DATE ART UNIT

January 3, 2005

		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	1
/CMW/	BOI	JP 5-246885	09/24/93	JP-A Kokai		
/CMW/	B02	WO 94/24160	10/27/94	Brigham and Women's Hospital		_
/CMW/	B03	WO 95/05465	02/23/95	Amgen, Inc.		Т
	D04	WO 97/18318	05/22/97	Takara Shuzo Co Ltd		
/CMW/	B05	WO 97/32895	12/12/97	Regents of the University of California		
/CMW/	B06	WO 98/18926	05/07/98	G.D. Searle & Co.		
	D07	WO.00/35475	06/22/00	Ehrenreich		
/CMW/	B08	WO 01/82952	11/08/01	Action Pharma APS		-
- 1	B09	WO 01/82953	11/08/01	Action Pharma APS		
	B10	EP 555880	08/18/93	Bristol-Myers Squibb Company		-
1/	BII	WO 92/08493	5/29/92	Brigham & Women's Hospital		Н
	B12	WO 96/14081	5/17/96	Boehringer Manheim gmbh		_
/CMW/	B13	WO 02/10743	2/07/02	Ortho-McNeil Pharmaceutical, Inc.		Н

#### NON PATENT LITERATURE DOCUMENTS Examiner Initials (Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.) т ALAFACI et al., 2000, "Effect of Recombinant Human Erythropoietin on Cerebral Ischemia Following COL /CMW/ Experimental Subarachnoid Hemorrhage," Eur. J. Phar., 406:219-225. ANAGNOSTOU et al., 1994, "Erythropoietin receptor mRNA expression in human endothelial cells", Proc. C02 Natl. Acad. Sci. USA 91:3974-3978 ANNABLE et al., 1972, "The Second International Reference Preparation of Erythropoietin, Human, Urinary, C03 for Bioassay," Bull. Org. mond. Sante, 47:99-112. ASHWELL et al., 1978, "A Protein from Mammalian Liver that Specifically Binds Galactose-Terminated C04 Glycoproteins," Meth. Enzymol., 50:287-291. BAUER, 1995, "The Oxygen Sensor That Controls EPO Production: Facts and Fancies," J. Perinat. Med., 23:7-C05 BENYO et al., 1999, "Expression of erythropoietin receptor by trophoblast cells in the human placenta", Biol. C06 Reproduct. 60:861-870 BERNAUDIN et al., 1999, "A potential role for erythropoietin in focal permanent cerebral ischemia in mice", J. C07 Cereb. Blood Flow Metab. 19:643-651 BERNAUDIN et al., 2000, "Neurons and astrocytes express EPO mRNA: oxygen-sensing mechanisms that C08 involve the redox-state of the brain", Glia 30:271-278 BONDY, 1995, "The relaxation of oxidative stress and hyperexcitation to neurological disease", Proc. Soc. Exp. COS /CMM/ Biol. Med. 208:337-345

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UVI	201	122		

/Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

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Express Mail No.: ED 608 969 335 US

Sheet 3 of 7 of List of References

# ATTY. DOCKET NO. 10165-037-999 10/520,140 LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) Filing DATE January 3, 2005 1647

		NOV BATTENT A ITTEN ATTITUDE DOCUMENTO	
	,	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	Т
/CMW/	C10	BRIGGS et al., 1974, "Hepatic Clearance of Intact and Desialylated Erythropoietin," Am. J. Physiol., 227:1385-1388.	
	CII	BRINES et al., 2000, "Erythropoietin crosses the blood-brain barrier to protect against experimental brain injury", Proc. Natl. Acad. Sci. USA 97:10526-10531	
	CI2	BRUNEVAL et al., 1993, "Erythropoietin Synthesis by Tumor Cells in a Case of Meningioma Associated With Erythrocytosis," Blood, 81:1593-1597.	
	C13	CAMISCOLI et al., 1968, "Comparative Assay of Erythropoietin Standards," Annals New York Acad. Sci., 149:40-45.	
	C14	CAMPANA et al., 1998, "Identification of a neurotrophic sequence in erythropoietin", Int. J. Mol. Med. 1:235-241	
	C15	CLAUS-WALKER et al., 1984, "Spinal Cord Injury and Serum Erythropoietin," Arch. Phys. Med. Rehabil., 65:370-374.	
	C16	COTES, 1968, "Quantitative Estimation of Erythropoietin," Part I. Assay and Standardization of Erythropoietin, Annals New York Acad. Sci., 149:12-17.	
	C17	COTES et al., 1961, "Bio-Assay of Erythropoietin in Mice Made Polycythaemic By Exposure to Air at a Reduced Pressure," Nature, 191:1065-1067.	
	C18	COTES et al., 1966, "The International Reference Preparation of Erythropoietin," Bull. Org. mond. Sante, 35:751-760.	
	C19	DIAZ-BRINTON et al., 1998, "Advances and challenges in the prevention and treatment of Alzheimer's disease," Pharm. Res. 15(3):386-98	
	C20	DIGICAYLIOGLU et al. 1995, "Localization of specific erythropoietin binding sites in defined areas of the mouse brain.", Proc. Natl. Acad. Sci. USA 92:3717-3720	
	C21	DIPAOLO et al., 1992, "Effects of uremia and dialysis on brain electrophysiology after recombinant erythropoietin treatment", ASAIO J. 38:M477-M480	
	C22	DONG et al., 1992, "Receptor binding of asialoerythropoietin," J. Cell. Biochem. 48(3):269-76	
	C23	DORDAL et al., 1985, "The Role of Carbohydrate in Erythropoietin Action," Endocrinol., 116:2293-2299.	
	C24	DUBE et al, 1988, "Glycosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," J. Biol. Chem., 263:17516-17521.	
	C25	EHRENREICH et al., 2002, "Erythropoietin therapy for acute stroke is both safe and beneficial", Molec. Med. 8(8):495-505	
	C26	Eur. Pharmacopoeia, 1997, p. 5.	
	C27	Eur. Pharmacopoeia, Suppl. 2001, pp. 777-782.	T
	C28	FARRELL et al., 2001, "Erythropoietin crosses the blood brain barrier", Blood 98:148b (abstr. # 4265; 43rd Annual Meeting of the American Society of Hematology, Orlando FL, Dec. 7-11, 2001)	
	C29	FEIGIN et al., 2002, "Recent advances in Huntington's disease: implications for experimental therapeutics," Curr. Opin. Neurol. 15(4):483-9	
	C30	FUKUDA et al., 1989, "Survival of Recombinant Erythropoietin in the Circulation: The Role of Carbohydrates," Blood, 73:84-89.	
V	C31	GARTHOFF, 1995, "Safety and Efficacy Testing of Hormones and Related Products," The Report and Recommendations of ECVAM Workshop 9, A.T.L.A., 23:699-711	
/CMW/	C32	GOLDWASSER et al., 1974, "On the Mechanism of Erythropoietin-Induced Differentiation," XIII. The Role of Sialic Acid in Erythropoietin Action, J. Biol. Chem., 249:4202-4206.	

EXAMINER NYI-3972311v2 /Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

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Sheet 4 of 7 of List of References

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 10165-037-999	APPLICATION NO. 10/520,140	
APPLICANT		
Brines et al.		
FILING DATE	ART UNIT	
January 3, 2005	1647	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	т
/CMW/	C33	GOLDWASSER et al., 1975, "An Assay for Erythropoietin in Vitro at the Milliunit Level," Endo., 97:315-323.	
	C34	GOLDWASSER et al., "Erythropoietin: Assay and Study of Its Mode of Action," Hormone Assays, pp. 109- 121.	
	C35	GORIO et al., 2002, "Recombinant human erythropoietin countenacts secondary injury and markedly enhances neurological recovery from experimental spinal cord trauma", Proc. Natl. Acad. Sci. USA 99:9450-9455 (PNAS Early Edition www.pnas.org/egi/doi/10.1073/pnas.142287899)	
	C36	GRASSO et al., 2002, "Beneficial effects of systemic administration of recombinant human erythrpoietin in rabbits subjected to subarachnoid hemorrhage", Proc. Natl. Acad. Sci. USA 99:5627-5631	
	C37	GREGORY et al., 1999, "GATA-1 and erythropoictin cooperate to promote erythroid cell survival by regulating bcl-xL expression", Blood 94:87-96	
	C38	GRIMM et al., 1990, "Improvement of brain function in hemodialysis patients treated with erythropoietin", Kidney Intl. 38:480-486	
	C39	HAMMOND et al., 1968, "Production, Utilization and Excretion of Erythropoietin: 1. Chronic Anemias. II. Aplastic Crisis. III. Erythropoietic Effects of Normal Plasma," Erythropoietin, 149:516-527.	
	C40	HEFTI, 1997, "Pharmacology of neurotrophic factors", Annu. Rev. Pharmacol. Toxicol. 37:239-267	
	C41	HENGEMIHLE et al., 1996, "Chronic treatment with human recombinant erythropoietin increases hematocrit and improves water maze performance in mice", Physiol. Behav. 59:153-156	
	C42	with recombinant human EPO", Am. J. Physiol. 262:F737-F743	
	C43	HORTON et al., 1991, "Von Hippel-Lindau Disease and Erythrocytosis: Radioimmunoassay of Erythropoietin in Cyst Fluid From a Brainstem Hemangioblastoma," Neurology, 41:753-754.	
	C44	IMAI et al., 1990, "Physicochemical and Biological Characterization of Asialoerythropoietin," Eur. J. Biochem., 194:457-462.	
	C45	JOOSS et al., 1996, "Cyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung," Hum. Gene Ther. 7(13):1555-66	
	C46	JUNK et al., 2002, "Erythropoietin administration protects retinal neurons from acute ischemia-reperfusion linjury", Proc. Natl. Acad. Sci. USA 99:10659-10664 (PNAS Early Edition www.pnas.org/egi/doi/10.1073/pnas.152321399)	
	C47	JUUL et al., 1998, "Erythropoietin and crythropoietin receptor in the developing human central nervous system", Pediatr. Res. 43:40-49	
	C48	JUUL et al., 1998, "Tissue distribution of erythropoietin and erythropoietin receptor in the developing human fetus", Early Human Devel. 52:235-249	
	C49	JUUL et al., 2001, "Recombinant erythropoietin (EPO) crosses the blood brain barrier (BBB) in preterm fetal sheep", Soc. for Neuroscience Abstracts 27:929 (31st Annual Meeting of the Society for Neuroscience, San Diego, CA Nov. 10-15, 2001)	
	C50	KEIGHLEY, 1968, "Further Experiences with Assays, Units, and Standards of Erythropoietin," Annals New York Acad. Sci., 149:18-24.	
	C51	KOHAMA et al., 2000, "Large Uterine Myoma with Erythropoietin Messenger RNA and Erythrocytosis," Obstetrics and Gynecology, 96:826-828.	
V	C52	KONISHI et al., 1993, "Trophic effect of erythropoietin and other hematopoietic factors on central cholinergic neurons in vitro and in vivo", Brain Res. 609:29-35	
/CMW/	C53	KOPF et al., 1994, "Memory improving actions of glucose: involvement of a central cholinergic muscarinic mechanism.", Behav. Neural Biol. 62:237-243	

EXAMINER NYI-3972311v2 /Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 5 of 7 of List of References

# ATTY. DOCKET NO. 10165-037-999 10/520,140 LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) Filmo date January 3, 2005 1647

		NON PATENT LITERATURE DOCUMENTS	
xaminer	T		
nitials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
CMW/	C54	LATINI et al., 1998, "Comparative efficacy of a DA2/α2 agonist and a β blocker in reducing adrenergic drive and cardiac fibrosis in an experimental model of left ventricular dysfunction after coronary artery occlusion", J. Cardiovasc. Pharmacol. 31:601-608	
	C55	LI et al., 1996, "Erythropoietin receptors are expressed in the central nervous system of mid-trimester human fetuses", Pediatr. Res. 40:376-380	Γ
	C56	LI et al., 1998, "A single pre training glucose injection induces memory facilitation in rodents performing various tasks: contribution of acidic fibroblast growth factor", Neurosci. 85:785-794	
	C57	LIPINSKI et al., 1995, "Nerve growth factor facilitates conditioned taste aversion learning in normal rats", Brain Res. 692:143-153	
	C58	LIU et al., 1996, "Transgenic mice containing the human erythropoietin receptor gene exhibit correct hematopoietic and neural expression", Proc. Assoc. Am. Physicians 108:449-454	
	C59	LIU et al., 1997, "Regulated human erythropoietin receptor expression in mouse brain", J. Biol. Chem. 272:32395-32400	
	C60	LIU et al., 1994, "Tissue specific expression of human erythropoietin receptor in transgenic mice", Devel. Biol. 166:159-169	
	C61	LOWY et al., 1960, "Inactivation of Erythropoietin by Neuraminidase and by Mild Substitution Reactions," Nature, 185:102-103.	
	C62	MARRERO et al., 1998, "Erythropoietin receptor-operated Ca2+ channels: activation by phospholipase C-y1", Kidney Intl. 53:1259-1268	
	C63	MARSH et al., 1991, "rHuEPO treatment improves brain and cognitive function of anemic dialysis patients", Kidney Intl. 39:155-163	
	C64	MARTI et al., 1997, "Detection of erythropoietin in human liquor: intrinsic erythropoietin production in the brain", Kidney Intl. 51:416-418	
	C65	MARTI et al., 1996, "Erythropoietin gene expression in human, monkey and murine brain", Eur. J. Neurosci. 8:666-676	
	C66	MASUDA et al., 1997, "Insulin like growth factors and insulin stimulate erythropoietin production in primary cultured astrocytes", Brain Res. 746:63-70	
	C67	MASUDA et al., 1994, "A novel site of erythropoietin production. Oxygen dependent production in cultured rat astrocytes", J. Biol. Chem. 269:19488-19493	Γ
	C68	MASUDA et al., 1993, "Functional erythropoietin receptor of the cells with neural characteristics. Comparison with receptor properties of erythroid cells", J. Biol. Chem. 268:11208-11216	
	C69	MATSUYAMA et al., 2000, "Erythrocytosis Caused by an Erythropoietin-Producing Hepatocellular Carcinoma," J. Surg. Oncology, 75:197-202.	Γ
	C70	MIONI et al., 1992, "Evidence for specific binding and stimulatory effects of recombinant human erythropoietin on isolated adult rat Leydig cells", Acta Endocrinologica 127:459-465	
	C71	MIYAKE et al., 1977, "Purification of Human Erythropoietin," J. Biol. Chem., 252:5558-5564.	
	C72	MORELL et al., 1968, "Physical and Chemical Studies on Ceruloplasmin," Metabolic Studies on Sialic Acid- Free Ceruloplasmin In Vivo, J. Biol. Chem., 243:155-159.	
	C73	MORISHITA et al., 1997, "Erythropoietin receptor is expressed in rat hippocampal and cerebral cortical neurons, and erythropoietin prevents in vitro glutamate induced neuronal death", Neurosci. 76:105-116	
$\sqrt{}$	C74	MOSS et al., 1996, "Oxygen administration enhances memory formation in healthy young adults", Psychopharmacol. 124:255-260	
/CMW/	C75	NAKAMURA et al., 1998, "Elevated levels of erythropoietin in cerebrospinal fluid of depressed patients", Am.	

EXAMINER /Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

\*EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 6 of 7 of List of References

# LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) APPLICANT Brines et al. FILING DATE January 3, 2005 1647

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials /CMW/		(include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)  J. Med. Sci. 315:199-201	Т
/OINIVI/	C76	NISSENSON et al., 1991, "Recombinant human erythropoietin and renal anemia: molecular biology, clinical efficacy and nervous system effects", Ann. Int. Med, 114:402-416	╁
	C77	NISSENSON, 1989, "Recombinant human erythropoietin: impact on brain and cognitive function, exercise tolerance, sexual potency and quality of life", Sem. Nephrol. 9(suppl. 2):25-31	$\vdash$
	C78	OGDEN, 1989, "Monitoring considerations in recombinant human erythropoietin therapy", Sem. Nephrol. 9(suppl. 2):12-15	Г
	C79	OKADA et al., 1996, "Erythropoietin stimulates proliferation of rat-cultured gastric mucosal cells", Digestion 57:328-332	Г
	C80	PARDRIDGE, 1997, "Drug delivery to the brain", J. Cerebral Blood Flow Metab. 17:713-731	
	C81	PARDRIDGE et al., 1991, "Selective transport of an anti-transferrin receptor antibody through the blood-brain barrier in vivo", J. Pharmacol. Exp. Ther. 27:66-70	
	C82	PLAPP et al., 1971, "Activity of bovine pancreatic deoxyribonuclease A with modified amino groups," J. Biol. Chem. 246(4):939-45	Г
	C83	PODUSLO et al., 1994, "Macromolecular premeability across the blood-nerve and blood-brain barriers", Proc. Natl. Acad. Sci. USA 91:5705-5709	
	C84	PRENDERGAST et al., 1997, "Nitric oxide synthase inhibition impairs spatial navigation learning and induces conditioned taste aversion", Pharmacol. Biochem. Behav. 57:347-352	
	C85	ROBINSON et al., 1975, "Tetanus toxin. The effect of chemical modifications on toxicity, immunogenicity, and conformation," J. Biol. Chem. 250(18):7435-42	1
	C86	ROSE et al., 1998, "Receptor-mediated angiotensin II transcytosis by brain microvessel endothelial cells", Peptides 19:1023-1030	
	C87	SADAMATO et al., 1998, "Erythropoietin prevents place navigation disability and cortical infarction in rats with permanent occlusion of the middle cerebral artery", Biochem. Biophys. Res. Comm. 253:26-32	
	C88	SAKANAKA et al., 1998, "In vivo evidence that erythropoietin protects neurons from ischemic damage", Proc. Natl. Acad. Sci. USA 95:4635-4640	
	C89	SATAKE et al. 1990, "Chemical modification of erythropoietin: an increase in in vitro activity by guanidination," Biochim. Biophys. Acta. 1038(1):125-9	
	C90	SAWYER et al., 1989, "Receptors for erythropoietin in mouse and human erythroid cells and placenta", Blood 74:103-109	
	C91	SHIRAMIZU et al., 1994, "Constitutive Secretion of Erythropoietin by Human Renal Adenocarcinoma Cells in Vivo and in Vitro," Exp. Cell Res., 215:249-256.	
	C92	SHORE et al., 1968, "Quantitative Estimation of Erythropoietin," Annals New York Acad. Sci., 149:46-48.	1
	C93	SILVA et al., 1999, "Erythropoietin can induce the expression of bcl-xL through Stat5 in erythropoietin- dependent progenitor cell lines", J. Biol. Chem. 274:22165-22169	T
	C94	SIRÉN et al., 2001, "Erythropoietin prevents neuronal apoptosis after cerebral ischemia and metabolic stress", Proc. Natl. Acad. Sci. USA 98:4044-4049	
	C95	SPIVAK et al., 1989, "The In Vivo Metabolism of Recombinant Human Erythropoietin in the Rat," Blood, 73:90-99.	Г
	C96	STARK et al., 1960, "Reactions of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-3181	T
/CMW/	C97	STEECE-COLLIER et al., 2002, "Etiology of Parkinson's disease: Genetics and environment revisited," Proc.	T

EXAMINER NYI-3972311v2 /Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 7 of 7 of List of References

	ATTY. DOCKET NO. 10165-037-999	APPLICATION NO. 10/520,140
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT Brines et al.	
	FILING DATE January 3, 2005	ART UNIT

		NON PATENT LITERATURE DOCUMENTS	
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Initials /CMV	,,	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
CIVIV	v/	Natl. Acad. Sci. U. S. A. 99(22):13972-4	
1	C98	STORRING et al., 1998, "Epoietin Alfa and Beta Differ In Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100:79-89.	
	C99	STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134:459-484.	
	C100	SUZUKI et al., 2001, "Erythropoietin Synthesis by Tumour Tissues in a Patient With Uterine Myoma and ERythrocytosis," British J. Haematology, 113:49-51.	
	C101	TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-252	
T	C102	WEILAND et al., "In vivo Activity of Asialo-Erythropoietin in Combination with Asialo-Glycoproteins," 1982, Blut, 44:173-175.	
Т	C103	WESTENFELDER et al., 1999, "Human, rat and mouse kidney cells express functional erythropoietin receptors", Kidney Intl. 55:808-820	
	C104	WILLIAMS et al., 1994, "Human erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244	
	C105	WOLCOTT et al., 1989, "Recombinant human erythropoietin treatment may improve quality of life and cognitive function in chronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485	
	C106	WU et al., 1999, "Neuroprotection with noninvasive neurotrophin delivery to the brain", PNAS 96:254-259	
V	C107	YAMAJI et al., 1996, "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA", Eur. J. Biochem. 239:494-500	
/CMV	// C108	YANG et al., 2002, "Effects of ammonia and glucosamine on the heterogeneity of erythropoietin glycoforms," Biotechnol. Prog. 18(1):129-38	

EXAMINER NYI-3972311v2
NY1-3972311v2

/Cherie M. Woodward/

DATE CONSIDERED

12/21/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 1 of 7 of List of References

ATTY. DOCKET NO. APPLICATION NO. 10/520,140 (National Stage of 10165-037-999 PCT/US2003/021350)

APPLICANT Brines et al.

> FILING DATE ART UNIT January 3, 2005 1647

REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

#### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
/CMW/	A01	4,377,513	03/22/83	Sugimoto et al.	
	A02	4,703,008	10/27/87	Lin	
	A03	4,806,524	02/21/89	Kawaguchi et al.	
	A04	4,835,260	05/30/89	Shoemaker	
	A05	5,457,089	10/10/95	Fibi et al.	
	A06	5,547,933	08/20/96	Lin	
	A07	5,571,787	11/05/96	O'Brien et al.	
	A09	5,614,184	03/25/97	Sytkowski et al.	
	A09	5,618,698	04/08/97	Lin	
	A10	5,621,080	04/15/97	Lin	
	A13	5,625,035	03/25/97	Clemons	
	A17	5,661,125	08/26/97	Strickland	
	A13	5,696,080	12/09/97	O' Brien	
	A13	5,700,909	12/23/97	O'Brien	
	A15	5,714,459	02/03/98	O'Brien	
	A10	5,756,349	05/26/98	Lin	
	A17	5,767,078	06/16/98	Johnson et al.	
	A18	5,773,569	06/30/98	Wrighton et al.	
	A19	5,830,851	11/03/98	Wrighton et al.	
	A20	5,835,382	11/10/98	Wilson et al.	
	A23	5,856,298	01/05/99	Strickland	
	A22	5,888,772	03/30/99	Okasinski et al.	
	A23	5,955,422	09/21/99	Lin	
V	A24	6,165,783	12/26/00	Weiss et al.	
/CMW/	A25	4,658,019	04/14/87	Kung et al.	

#### FOREIGN PATENT DOCUMENTS

EXAMINER 12/21/2007 /Cherie M. Woodward/ DATE CONSIDERED NYI-3972311v2

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 2 of 7 of List of Reference

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATY. DOCKET NO. 10/520,140
(National Stage of PCT/US2903/021350)

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Brines et al.

FILING DATE
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APPLICANT

Brines et al.

	FOREIGN PATENT ACCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	т
B01	JP 5-246883	09/24/93	JP-A Kokai		
B02	WO 94/24160	10/27/94	Brigham and Women's Hospital		
B03	WO 95/05465	02/23/95	Amgen, Inc.		
B04	WO 97/18318	05/22/97	Takara Shuzo Co., Ltd.		
B05	WO 97/32895	12/12/97	Regents of the University of California		
B06	WO 98/18926	06/07/98	G.D. Searle & Co.		
B07	WO 00/35475	06/22/00	Ehrenreich		
B08	WO 01/82952	11/08/01	Action Pharma APS		
B09	WO 01/82953	11/08/01	Action Pharma APS		
B10	EP 555880	08/18/93	Bristol-Myers Squibb Company		
BII	WO 92/08493	5/29/92	Brigham & Women's Hospital		
B12	WO 96/14081	5/17/96	Boenringer Manheim gmbh		1
B13	WO 02/10743	2/07/02	Orthe-McNeil Pharmaceutical, Inc.		

#### NON PATENT LITERATURE DOCUMENTS Examiner (Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.) Т Initials ALAFACI et al., 2000, "Effect of Recombinant Human Erythopoletin on Cerebral Ischemia Following Experimental Subarachnoid Hemorrhage," Eur. J. Phar., 406:219-225. COL ANAGNOSTOU et al., 1994, "Erythropoietin receptor mRNA expression in human endothelial cells". Proc. C02 Natl. Acad. Sci. USA 91:2974-3978 ANNABLE et al., 1972 The Second International Reference Preparation of Erythropoietin, Human, Urinary, C03 for Bioassay," Bull. Og. mond. Sante, 47:99-112. ASHWELL et al., 178, "A Protein from Mammalian Liver that Specifically Binds Galactose-Terminated Glycoproteins," Meth. Enzymol., 50:287-291. BAUER, 1995, The Oxygen Sensor That Controls EPO Production: Facts and Fancies," J. Perinat. Med., 23:7-C04 C05 12. BENYO et al., 1999, "Expression of erythropojetin receptor by trophoblast cells in the human placenta". Biol. C06 Reproduct. 60:861-870 BERNAUDIN et al., 1999, "A potential role for erythropoietin in focal permanent cerebral ischemia in mice". J. C07 Cereb Blood Flow Metab. 19:643-651 BEXNAUDIN et al., 2000, "Neurons and astrocytes express EPO mRNA: oxygen-sensing mechanisms that involve the redox-state of the brain", Glia 30:271-278 BONDY, 1995, "The relaxation of oxidative stress and hyperexcitation to neurological disease", Proc. Soc. Exp.

EXAMINER NYI-39/2311v2	DATE CONSIDERED

Biol. Med. 208:337-345

\*XAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and be considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 164 Express Mail No.: DRAFT Sheet 3 of 7 of List of References

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ATTY, DOCKET NO.	APPLICATION NO.
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# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

# NON PATENT LITERATURE DOCUMENTS

Examiner			
Initials	1	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, etc.)	T
	C10	BRIGGS et al., 1974, "Hepatic Clearance of Intact and Desialylated Erythropaletin," Am. J. Physiol., 227:1385-1388.	
	CH	BRINES et al., 2000, "Erythropoietin crosses the blood-brain barrier to potect against experimental brain injury", Proc. Natl. Acad. Sci. USA 97:10526-10531	
	C12	BRUNEVAL et al., 1993, "Erythropoletin Synthesis by Tumor Cells in a Case of Meningioma Associated With Erythrocytosis," Blood, 8 N 593-1597.	
	C13	CAMISCOLI et al., 1968, "Comparative Assay of Erythropoietin Standards," Annals New York Acad. Sci., 149:40-45.	
	C14	CAMPANA et al., 1998, "Identification of a neurotrophic sequence in erythropoietin", Int. J. Mol. Med. 1:235-241	
	C15	CLAUS-WALKER et al., 1984, "Spinal Cord Injury and Gerum Erythropoietin," Arch. Phys. Med. Rehabil., 65:370-374.	П
	C16	COTES, 1968, "Quantitative Estimation of Erythropoletin," Part I. Assay and Standardization of Erythropoletin, Annals New York Acad. So., 149:12-17.	
	C17	COTES et al., 1961, "Bio-Assay of Erythropoletic in Mice Made Polycythaemic By Exposure to Air at a	
	C18	COTES et al., 1966, "The International Reference Preparation of Erythropoietin," Bull. Org. mond. Sante, 35:751-760.	
	C19	DIAZ-BRINTON et al., 1998, "Advance and challenges in the prevention and treatment of Alzheimer's disease," Pharm. Res. 15(3):386-98	
	C20	DIGICAYLIOGLU et al. 1995, "Localization of specific prythropoietin binding sites in defined areas of the mouse brain.", Proc. Natl. Acad. Spi. USA 92:3717-3720	
	C24	DIPAOLO et al., 1992, "Effects of uremia and dialysis on brain electrophysiology after recombinant erythropoletin treatment", ASAIO J. 38:M477-M480	Т
	C22	DONG et al., 1992, "Receptor binding of asialoerythropoietin," J. Cell. Biochem. 48(3):269-76	$\overline{}$
	C23	DORDAL et al., 1985, "The Role of Carbohydrate in Erythropoietin Action," Endocrinol., 116:2293-2299.	$\top$
	C24	DUBE et al, 1988, "Gl/cosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," J. Biol. Chem., 263:17516-17521.	
	C25	EHRENREICH et al., 2002, "Erythropoietin therapy for acute stroke is both safe and beneficial", Molec. Med. 8(8):495-505	
	C26	Eur. Pharmacopoeia, 1997, p. 5.	
	C27	Eur. Pharms Copoeia, Suppl. 2001, pp. 777-782.	
	C28	FARREL L et al., 2001, "Erythropoietin crosses the blood brain barrier", Blood 98:14b (abstr. # 4265; 43rd Annual Meeting of the American Society of Hematology, Orlando FL, Dec. 7-11, 2001)	
	C29	FEIQIN et al., 2002, "Recent advances in Huntington's disease: implications for experimental therapeutics," Cur. Opin. Neurol. 15(4):483-9	
	C30	DUKUDA et al., 1989, "Survival of Recombinant Erythropoietin in the Circulation: The Role of Carbohydrates," Blood, 73:84-89.	
	C31	GARTHOFF, 1995, "Safety and Efficacy Testing of Hormones and Related Products," The Report and	

EXAMINER NY1-3972311v2

<sup>\*</sup>EAAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and no considered. Include copy of this form with next communication to applicant.



	ATTY. DOCKET NO.	APPLICATION NO. 10/520,140 (National Stage of
EFFDENCES CITED BY ADDITIONT	10165-037-999	PCT/US2/03/021350)
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# NON PATENT LITERATURE DOCUMENTS

LIST OF

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	т
IIIIIII	_	Recommendations of ECVAM Workshop 9, A.T.L.A., 23:699-711	Ė
	C32	GOLDWASSER et al., 1974, "On the Mechanism of Erythropoietin-Induged Differentiation," XIII. The Role of Sialic Acid in Erythropoietin Action, J. Biol. Chem., 249:4202-4206.	
	C33	GOLDWASSER et al. 1975, "An Assay for Erythropoietin in Vitro at the Milliunit Level," Endo., 97:315-323.	
	C34	GOLDWASSER et al., "Frythropoietin: Assay and Study of Its Mode of Action," Hormone Assays, pp. 109- 121.	
	C35	GORIO et al., 2002, "Recombinant human erythropoietin countracts secondary injury and markedly enhances neurological recovery from exherimental spinal cord trauma? Proc. Natl. Acad. Sci. USA 99:9450-9455 (PNAS Early Edition www.pnas.org/eg/bol/10.1073/pnas.14228799)	
Ch.	C38	GRASSO et al., 2002, "Beneficial affects of systemic administration of recombinant human erythrpoietin in rabbits subjected to subarachnoid henorrhage", Proc. Matl. Acad. Sci. USA 99:5627-5631	
	C38	GREGORY et al., 1999, "GATA-1 and crythropoietid cooperate to promote crythroid cell survival by regulating bel-xL expression", Blood 94:87-96	
	C38	GRIMM et al., 1990, "Improvement of brain function in hemodialysis patients treated with erythropoietin", Kidney Intl. 38:480-486	
	C38	HAMMOND et al., 1968, "Production, Utilication and Excretion of Erythropoietin: 1. Chronic Anemias. II. Aplastic Crisis. III. Erythropoietic Effects of Normal Plasma," Erythropoietin, 149:516-527.	
	C40	HEFTI, 1997, "Pharmacology of neurotrophic factors", Annu. Rev. Pharmacol. Toxicol. 37:239-267	$\Box$
	C41	HENGEMIHLE et al., 1996, "Chroni treatment with suman recombinant erythropoietin increases hematocrit and improves water maze performance in mice", Physiol. Behav. 59:153-156	
	C42	HIRAKATA et al., 1992, "CBF and oxygen metabolism in hemodialysis patients: effects of anemia correction with recombinant human EPO" Am. J. Physiol. 262:F737-1743	
	C43	HORTON et al., 1991, "Von dippel-Lindau Disease and Erythrocytosis: Radioimmunoassay of Erythropoietin in Cyst Fluid From a Brainstem Hemangioblastoma," Neurology 41:753-754.	
	C44	IMAI et al., 1990, "Physicochemical and Biological Characterization of Asialoerythropoietin," Eur. J. Biochem., 194:457-462.	
	C45	JOOSS et al., 1996, "Cyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung," Hum. Gene The., 7(13):1555-66	
	C46	JUNK et al., 2000. "Erythropoietin administration protects retinal neurons from acute ischemia-reperfusion injury", Proc. Dyd. Acad. Sci. USA 99:10659-10664 (PNAS Early Edition www.pnas.or/cgi/doi/10.1073/pnas.152321399)	
	C47	JUUL et al. 1998, "Erythropoietin and erythropoietin receptor in the developing human central nervous system", ediatr. Res. 43:40-49	
	C48	JUUL of al., 1998, "Tissue distribution of erythropoietin and erythropoietin receptor in the developing human fetus", Early Human Devel. 52:235-249	
	C49	JUYL et al., 2001, "Recombinant erythropoietin (EPO) crosses the blood brain barrier (ABB) in preterm fetal skeep", Soc. for Neuroscience Abstracts 27:929 (31st Annual Meeting of the Society for Neuroscience, San Diego, CA Nov. 10-15, 2001)	
	C50	KEIGHLEY, 1968, "Further Experiences with Assays, Units, and Standards of Erythropoietin," Annals New York Acad. Sci., 149:18-24.	

N	1-39/2311v2	DATE CONSIDERED		
	AMINER: Initial if reference considered, whether or not citation is in conformal sidered. Include copy of this form with next communication to applicant.	nce with MPEP 609; Draw line through citation if not in conformance	and n	ot

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 5 of 7 of List of References

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO. | APPLICATION NO. 10/520,140 (National Stage of PCT/US2005/021350)

APPLICANT | Brines et al. | FILING DATE | ARTICINIT | January 3, 2005 | J647

#### NON DATENT LITTED ATLIDE DOCUMENTS

Examiner			г
Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	т
	C51	KOHAMA et al. 2000, "Large Uterine Myoma with Erythropoietin Messenger RNA and Erythrocytosis," Obstetrics and Gyaecology, 96:826-828.	
	C52	KONISHI et al., 1933, "Trophic effect of crythropoietin and other hematopoietic factors on central cholinergic neurons in vitro and it vivo", Brain Res. 609:29-35	
	C53	KOPF et al., 1994, "Metuory improving actions of glucose: involvement of a central cholinergic muscarinic mechanism.", Behav. Neural Biol. 62:237-243	
	C54	LATINI et al., 1998, "Comparative efficacy of a DA2/α2 agonist and a β blocker in reducing adrenergic drive and cardiac fibrosis in an experimental model of left ventricular systunction after coronary artery occlusion", J. Cardiovasc. Pharmacol. 31:601-608	
	C58	LI et al., 1996, "Erythropoietin receptors are expressed in the central nervous system of mid-trimester human fetuses", Pediatr. Res. 40:376-380	
	C56	LI et al., 1998, "A single pre training Aucose injection induces memory facilitation in rodents performing various tasks: contribution of acidic fibrablast growth actor", Neurosci, 85:785-794	
	C58	LIPINSKI et al., 1995, "Nerve growth factor facilitates conditioned taste aversion learning in normal rats", Brain Res. 692:143-153	
	C58	LIU et al., 1996, "Transgenic mice containing the human erythropoietin receptor gene exhibit correct hematopoietic and neural expression", Proc. 255cc. Am. Physicians 108:449-454	
	C58	LIU et al., 1997, "Regulated human erythrosoietin receptor expression in mouse brain", J. Biol. Chem. 272:32395-32400	
	C60	LIU et al., 1994, "Tissue specific expression of human crythropoietin receptor in transgenic mice", Devel. Biol. 166:159-169	
	C61	LOWY et al., 1960, "Inactivation of Erythropoietin by Neoraminidase and by Mild Substitution Reactions," Nature, 185:102-103.	
	C62	MARRERO et al., 1998, "Eryth ropoietin receptor-operated Cas+ channels: activation by phospholipase C-y1", Kidney Intl. 53:1259-1268	
	C63	MARSH et al., 1991, "rHu/PO treatment improves brain and cognitive function of anemic dialysis patients", Kidney Intl. 39:155-163	
	C64	MARTI et al., 1997, "Detection of erythropoietin in human liquor: introsic erythropoietin production in the brain", Kidney Intl. 5:416-418	
	C65	MARTI et al., 1996, "Erythropoietin gene expression in human, monkey and murine brain", Eur. J. Neurosci. 8:666-676	
	C66	MASUDA et al., 1997, "Insulin like growth factors and insulin stimulate erythopoietin production in primary cultured astrocytes", Brain Res. 746:63-70	Г
	C67	MASUDA et al., 1994, "A novel site of erythropoietin production. Oxygen dependent production in cultured rat astrocytes", J. Biol. Chem. 269:19488-19493	
	C68	MASUDA et al., 1993, "Functional erythropoietin receptor of the cells with neural chalacteristics. Comparison with receptor properties of erythroid cells", J. Biol. Chem. 268:11208-11216	
	C69	MATSUYAMA et al., 2000, "Erythrocytosis Caused by an Erythropoietin-Producing Hepacocellular arcinoma," J. Surg. Oncology, 75:197-202.	
	C70	MIONI et al., 1992, "Evidence for specific binding and stimulatory effects of recombinant human erythropoietin on isolated adult rat Leydig cells", Acta Endocrinologica 127:459-465	

EXAMUSER NYI-39/2311v2	DATE CONSIDERED
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10520140 - GAU: 164 Express Mail No.: DRAFT Sheet 6 of 7 of List of References

ATTY. DOCKET NO. APPLICATION NO. 10/520,140 (National Stage of PCT/US2903/021350) 10165-037-999 LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) APPLICANT Brines et al. AP TUNIT FILING DATE 647 January 3, 2005

### NON PATENT LITERATURE DOCUMENTS

		NONTATENT EFFERATORE DOCUMENTS	
Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages (Etc.)	т
	C71	MIYAKE et al. 1977, "Purification of Human Erythropoietin," J. Biol. Cherg., 252:5558-5564.	Ė
	C72	MORELL et al., 1968, "Physical and Chemical Studies on Ceruloplasmin," Metabolic Studies on Sialic Acid- Free Ceruloplasmin, o Vivo, J. Biol. Chem., 243;155-159.	
	C73	MORISHITA et al., 1927, "Erythropoietin receptor is expressed in rat/hippocampal and cerebral cortical neurons, and erythropoietin prevents in vitro glutamate induced neuronal death", Neurosci. 76:105-116	
	C74	MOSS et al., 1996, "Oxygon administration enhances memory formation in healthy young adults", Psychopharmacol. 124:255-260	
	C75	NAKAMURA et al., 1998, "Elevated levels of erythropoietin in cerebrospinal fluid of depressed patients", Am. J. Med. Sci. 315:199-201	
	C76	NISSENSON et al., 1991, "Recomainant human erythrophietin and renal anemia: molecular biology, clinical efficacy and nervous system effects" Ann. Int. Med. 11:402-416	
	C77	NISSENSON, 1989, "Recombinant hunan erythropoictin: impact on brain and cognitive function, exercise tolerance, sexual potency and quality of Me", Sem. Nephrol. 9(suppl. 2):25-31	
	C78	OGDEN, 1989, "Monitoring considerations in recombinant human erythropoietin therapy", Sem. Nephrol. 9(suppl. 2):12-15	
	C78	OKADA et al., 1996, "Erythropoietin stimulates proliferation of rat-cultured gastric mucosal cells", Digestion 57:328-332	
	C80	PARDRIDGE, 1997, "Drug delivery to the brain", Cerebral Blood Flow Metab. 17:713-731	
	C81	PARDRIDGE et al., 1991, "Selective transport of an auti-transferrin receptor antibody through the blood-brain barrier in vivo", J. Pharmacol. Exp. Ther. 27:66-70	
	C82	PLAPP et al., 1971, "Activity of bavine pancreatic deoxyr bonuclease A with modified amino groups," J. Biol. Chem. 246(4):939-45	
1	C83	PODUSLO et al., 1994, "Macromolecular premeability across the blood-nerve and blood-brain barriers", Proc. Natl. Acad. Sci. USA 91:5795-5709	
	C81	PRENDERGAST et al., 1997, "Nitric oxide synthase inhibition impairs spatial navigation learning and induces conditioned taste aversion", Pharmacol. Biochem. Behav. 57:347-35	Г
	C85	ROBINSON et al., 1975, "Tetanus toxin. The effect of chemical modifications on toxicity, immunogenicity, and conformation," J. Biol. Chem. 250(18):7435-42	
	C85	ROSE et al., 1998 "Receptor-mediated angiotensin II transcytosis by brain microvessel endothelial cells", Peptides 19:1027-1030	Г
	C87	SADAMATOet al., 1998, "Erythropoietin prevents place navigation disability and cortical infarction in rats with permanent occlusion of the middle cerebral artery", Biochem. Biophys. Res. Comm. 253:26-32	
	C88	SAKANAKA et al., 1998, "In vivo evidence that erythropoietin protects neurons from ischemic damage", Proc. Natl. Acad. Sci. USA 95:4635-4640	
	C89	SATAKE et al. 1990, "Chemical modification of erythropoietin: an increase in in vitro activity by guandination," Biochim. Biophys. Acta. 1038(1):125-9	
	C90	SAWYER et al., 1989, "Receptors for erythropoietin in mouse and human erythroid cells and placenta", Blood 4:103-109	Γ
	C91	SHIRAMIZU et al., 1994, "Constitutive Secretion of Erythropoietin by Human Renal Adenocal cinoma Cells in Vivo and in Vitro," Exp. Cell Res., 215:249-256.	

EXAMINER NYI-39/2311v2	DATE CONSIDERED

<sup>\*</sup>FXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609, Draw line through citation if not in conformance and he considered. Include copy of this form with next communication to applicant.

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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	Brines et al.	
	FILING DATE	AR UNIT
	January 3, 2005	647

# NON PATENT LITERATURE DOCUMENTS

Initials   Cinclude name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Mc.)				
SILVA et al., 1991, "Erythropoietin can induce the expression of bct-xL through Stat5 in erythropoietin-dependent progenito cell lines", J. Biol. Chem. 274:22165-22169  G94 SIREN et al., 2001, "Porthropoietin prevents neuronal apoptosis after screbral ischemia and metabolic stress", Proc. Natl. Acad. Sci. Ush 98:4044-4049  G95 SPIVAK et al., 1989, "The Invitor Wetabolism of Recombinant Haman Erythropoietin in the Rat," Blood, 73:90-99.  G96 STARK et al., 1960, "Reaction of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318  G97 STEECE-COLLIER et al., 2002, "tiology of Parkinson's disease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22): 13372-4  G98 STORRING et al., 1989, "Epoietin Alth and Beta Differ in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100/29-89.  G99 STORRING et al., 1982, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-Derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol, 134 S-9484.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropoyetysis," British J. Haematology, 1,349-9-48.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematogoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devt. Neurosci. 13:241-25.  C102 WESTENPELDER et al., 1999 Pluman, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 5:889-520  C104 WILLIAMS et al., "1999, Recombinant human erythropoietin receptor," Ann. N.Y. Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoietin receptor," Ann. N.Y. Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoietin receptor, Neurotrophic organitive function in cylonic hemodalsysis patients", And. J. Kidney Obc., 14:478-485	Examiner Initials			т
dependent progenito cell lines", J. Biol. Chem. 274:22165-22169  (94)  SIRÉN et al., 2001, "Porthropoietin prevents neuronal apoptosis after gerebral ischemia and metabolic stress", Proc. Natl. Acad. Sci. Us. A 98:4044-4049  (95)  SPIVAK et al., 1989, "The In Vivo Metabolism of Recombinant Haman Erythropoietin in the Rat," Blood, 73:90-99.  (96)  STARK et al., 1980, "Reactions of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318.  (97)  STEECE-COLLIER et al., 2002, "kilology of Parkinson's disease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22):1302-4  (98)  STORRING et al., 1989, "Epoietin Alha and Beta Differ in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100/20-89.  STORRING et al., 1982, "The International Standard for Recombinant DNA-Derived Erythropoietins." Collaborative Study of Four Recombinant DNA derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134, 39-484.  C100  SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropoytosis," British J. Haematology, 10, 1349-59-484.  C101  TABIRA et al., 1995, "Neurotrophic effect of hematoloietic cytokines on cholinergic and other neurons in vitro", Int. J. Devi. Neurosci. 13:241-254.  C102  WELLAND et al., "In vivo Activity of Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Bill. 44:173-175.  C103  WESTENPELDER et al., 1999, "Neurotrophic in receptor", Ann. V.Y. Acad. Sci. 718:232-244  C105  WOLCOTT et al., 1989, Recombinant human erythropoletin raw in prove quality of life and cognitive function in option hemodalsysis patients", Am. J. Kidney Obs. 14:478-485		C92	SHORE et al., 1968, "Quantitative Estimation of Erythropoietin," Annals New York Acad. Sci., 149:46-48.	
Proc. Natl. Acad. Sci. U.A. 98:404-4049  OS SPIVAK et al., 1989, "Thelin Vivo Metabolism of Recombinant Haman Erythropoietin in the Rat," Blood, 73:90-99.  C96 STARK et al., 1960, "Reaction of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318.  C97 STARK et al., 1960, "Reaction of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318.  C98 STORRING et al., 1998, "Epotein Anh and Beta Driffer in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100/29-89.  C99 STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietins." Collaborative Study of Four Recombinant DNA-derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134, 59-484.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropovietis," British J. Haematology, 10, 134, 59-484.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-252.  C102 WELLAND et al., "In vivo Activity of Asialo-Erythropoietin in Combination with Asialo-Glycoproteins," 1982, Blut. 44:173-175.  C103 WESTENPELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 53:809-820.  C104 WILLIAMS et al., 1999, Recombinant human erythropoietin raturent may improve quality of life and cognitive function in grotein hemodalysis patients," And., J. Kidney Obs. 14:478-485		C93	dependent progenito cell lines", J. Biol. Chem. 274:22165-22169	
73:90-99.  C96 STARK et al., 1960, "Reaction of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318.  C97 STEEC-COLLIER et al., 2002, "kilology of Parkinson's disease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22):139-22-4  C98 STORRING et al., 1998, "Epotein Anh and Beta Diffs' in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100/29-89. C99 STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134, 59-348.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropoietysis," British J. Haematology, 10, 134, 59-348.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-25.  C102 WELLAND et al., "In vivo Activity of Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Blut. 44:173-175.  C103 WESTENPELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor", Kidney Intl. 53:809-820 C104 WILLIAMS et al., 1999, Recombinant human erythropoietin receptor", Ann. V. Acad. Sci. 718:232-244 C105 WOLCOTT et al., 1989, Recombinant human erythropoietin rathrent may improve quality of life and cognitive function in ground brother mediately spatients", Am. J. Kidney De., 14:478-485		C94	Proc. Natl. Acad. Sci. USA 98:4044-4049	
Biol. Chem. 235(11): 3177-318.  C97 STEECE-COLLIER et al., 2002, "kiology of Parkinson's fisease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22):130*2-4  C98 STORRING et al., 1998, "Epoietin Albq and Beta Diffyr in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100*20-89.  C99 STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134, 59-484.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropytosis," British J. Haematology, 13-49-34.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-252.  C102 WELLAND et al., "In vivo Activity of Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Blut. 44:173-175.  C103 WESTENPELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 53:809-820 C104 WILLIAMS et al., 1999, "Recombinant human erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244 C105 WOLCOTT et al., 1989, Recombinant human erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244 C105 WOLCOTT et al., 1989, Recombinant human erythropoietin remainer may improve quality of life and cognitive function in option hemodalsysis patients", Am. J. Kidney Dks. 14:478-485		C95	73:90-99.	
Natl. Acad. Sci. U. S. A. 190(22):130*2_4*  C98  STORRING et al., 1998, "Epoletin Alby and Beta Diffyf in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100*20-89.  C99  STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin." Collaborative Study of Four Recombinant DNA-Derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol. 134, 59-484.  C100  SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythropoietins," J. Haematology, J. 13-49-3-48.  C101  TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-252.  C102  WELLAND et al., "In vivo Activity of Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Blut. 44:173-175.  C103  WESTENPELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 53:809-820  C104  WILLIAMS et al., 1994, "Human erythropoietin receptor", Ann. V. Acad. Sci. 718:232-244  C105  WOLCOTT et al., 1989, Recombinant human erythropoietin may improve quality of life and cognitive function in groin hemodalsys patients", An. J. Kidney Obs. 14:478-485		C96	Biol. Chem. 235(11): 3177-318	
Properties," British J. Haematology, 100/20-89.  C99 STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-Derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134, 59-484.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythrocytosis," British J. Haematology, J. 13-49-34.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-252.  C102 WELLAND et al., "In vivo Activity of Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Blut, 41:73-175.  C103 WESTENFELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 53:809-820  C104 WILLIAMS et al., 1994, "Human erythropoietin receptor", Ann. VY Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoietin reaptor and the standard and cognitive function in grotnic hemodalsysis patients", An. J. Kidney Obs. 14:478-485		C97	Natl. Acad. Sci. U. S. A. 99(22):139 2-4	
Collaborative Study of Four Recombinant Di Aylerived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins, "J. Endocrinol., 134, 59-484.  C100 SUZUKI et al., 2001, "Erythropoietin Synthysis to Tumour Tissues in a Patient With Uterine Myoma and Erythrocytosis," British J. Haematology, 13-49-34.  C101 TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devi. Neurosci. 13:241-252.  C102 WELLAND et al., "In vivo Activity of Asialo-Erythropolutin in Combination with Asialo-Glycoproteins," 1982, Blut, 44:173-175.  C103 WESTENFELDER et al., 1999 y Human, rat and mouse kidney cells express functional erythropoietin receptor," Kidney Intl. 53:809-820  C104 WILLIAMS et al., 1994, "Human erythropoietin receptor", Ann. VY Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoietin raw improve quality of life and cognitive function in oftonic hemodialysis patients", An. J. Kidney Obs. 14:478-485		C98	Properties," British J. Haematology, 10079-89.	
ERythrocytosis," British J. Haematology, 13:49-3.  C101  TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro", Int. J. Devl. Neurosci. 13:241-32  C102  WEILAND et al., "In vivo Activity I Asialo-Erythropolitin in Combination with Asialo-Glycoproteins," 1982, Blut, 4:17-3-173.  C103  WESTENFELDER et al., 1999, Human, rat and mouse kidney cells express functional erythropoletin receptor," Kidney Intl. 55:809-820  C104  WILLIAMS et al., 1994, "Human erythropoletin receptor," Ann. NY Acad. Sci. 718:232-244  C105  WOLCOTT et al., 1989, Recombinant human erythropicitin treatment may improve quality of life and cognitive function in oftonic hemodalysis patients", Am. J. Kidney Qbc., 14:478-485		C99	Collaborative Study of Four Recombinant DNA derived Erythronoietins and Two Highly Purified Human	
vitro", Int. J. Devl. Neurosci. 13:241-32  C102 WEILAND et al., "In vivo Activity of Asialo-Erythropolytin in Combination with Asialo-Glycoproteins," 1982, Blut, 44:173-175.  C103 WESTENNELDER et al., 1999, Human, rat and mouse kidney cells express functional erythropoletin receptors", Kidney Intl. 55:809-820  C104 WILLIAMS et al., 1994, "Homan erythropoletin receptor", Ann. LY Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoletin treatment may improve quality of life and cognitive function in oftonic hemodialysis patients", Am. J. Kidney Dbs., 14:478-485		C100		
Blut, 44:173-173.  C103 WESTENFELDER et al., 1999 / Human, rat and mouse kidney cells express functional erythropoietin receptors", Kidney Intl. 55:80/820  C104 WILLIAMS et al., 1994. "Human erythropoietin receptor", Ann. VY Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989. Recombinant human erythropietin treatment may improve quality of life and cognitive function in cylonic hemodialysis patients", Am. J. Kidney Dbs., 14:478-485		C101	vitro", Int. J. Devl. Neurosci. 13:241-262	
receptors", Kidney Intl. 55:805' 20  C104 WILLIAMS et al., 1994, "Hyman erythropoietin receptor", Ann. VY Acad. Sci. 718:232-244  C105 WOLCOTT et al., 1989, Recombinant human erythropoietin treatment may improve quality of life and cognitive function in optonic hemodialysis patients", Am. J. Kidney Dis. 14:478-485		C102	Blut, 44:173-175.	
C105 WOLCOTT et al., 1989. Recombinant human erythropoietin treatment may improve quality of life and cognitive function in cyronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485		C103	WESTENFELDER et al., 1999 Human, rat and mouse kidney cells express functional erythropoietin receptors", Kidney Intl. 55:803-820	
cognitive function in chronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485		C104	WILLIAMS et al., 1994, "Haman erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244	
OLOG Willet al. 1999 "Negron rotection with noninvestive neurotrophin delivery to the brain" DNAS 96:254-259		C105		
C106 170 ct al., 1999, Treatopiotection with homitivasive neurotropini delivery to the orali , 11743 90.234-239		C106	WU et al., 1999, "Nearoprotection with noninvasive neurotrophin delivery to the brain", PNAS 96:254-259	
C107 YAMAJI et al., 1996, "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA", Eur. J. Biochem 239:494-500		C107	Eur. J. Biochem 239:494-500	Т
C108 YANG et al., 2002, "Effects of ammonia and glucosamine on the heterogeneity of erythropoietin glycoforms," Biotechnol. rog. 18(1):129-38		C108	YANG et al., 7002, "Effects of ammonia and glucosamine on the heterogeneity of erythropoietin glycoforms," Biotechnol. 7 og. 18(1):129-38	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

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#### ILS PATENT DOCUMENTS

*EXAMINER					PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT
INITIAL	101	4,377,513	DATE 03/22/83	NAME Sugimoto et al.	FIGURES APPEAR
	A01	4,703,008	10/27/87	Lin	
	A02				
	A03	4,806,524	02/21/89	Kawaguchi et al.	
	A04	4,835,260	05/30/89	Shoemaker	
	A05	5,457,089	10/10/95	Fibi et al.	
	A06	5,547,933	08/20/96	Lin	
	A07	5,571,787	11/05/98	O'Brien et al.	
	A08	5,614,184	03/25/97	Sytkowski et al.	
	A09	5,618,698	04/08/97	\(\frac{1}{2}\)	
	A10	5,621,080	04/15/97	Lin	
	A11	5,625,035	04/29/97	Clemens	
	A12	5,661,125	08/26/97	Strickland	
	Λ13	5,696,080	12/09/97	Ø' Brien	
	A14	5,700,909	12/23/97	O'Brien	
	A15	5,714,459	02/03/98	O'Brien	
	A16	5,756,349	05/26/98	Lin	
	A17	5,767,078	06/6/98	Johnson et al.	
	A18	5,773,569	6/30/98	Wrighton et al.	
	A19	5,830,851	11/03/98	Wrighton et al.	
	A20	5,835,382	11/10/98	Wilson et al.	
	A21	5,856,298	01/05/99	Strickland	
	A22	5,888,772	03/30/99	Okasinski et al.	
_	A23	5,955,422	09/21/99	Lin	
	A24	6,165,783	12/26/00	Weiss et al.	1
	A25	4,658,719	04/14/87	Kung et al.	1

#### FOREIGN PATENT DOCUMENTS

EXAMINAR NYL-3973611v2	DATE CONSIDERED	/

<sup>\*</sup>EX\_MINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 2 of 7 of List of References

ATTY. DOCKET NO. 10/520,140 (National System of PCT/US2/03/021350)

# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

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		January 3, 2005	1647	
POREIGN PATENT OCCUMENT COUNTRY CODE, NUM KIND CODE (IF KNO)	IBER,	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	т
B01 JP 5-24688	09/24/93	JP-A Kokai		
B02 WO 94/24160	10/27/94	Brigham and Women's Hospital		
B03 WO 95/05465	02/23/95	Amgen, Inc.		
B04 WO 97/18318	05/22/97	Takara Shuzo Co., Ltd.		
B05 WO 97/32895	12/12/97	Regents of the University of California		
B06 WO 98/18926	5/07/98	G.D. Searle & Co.		
B07 WO 00/35475	06/02/00	Ehrenreich		
B08 WO 01/82952	11/08/01	Action Pharma APS		
B09 WO 01/82953	11/08/0	Action Pharma APS		
B10 EP 555880	08/18/93	Bristol-Myers Squibb Company		
B11 WO 92/08493	5/29/92	Brigham & Women's Hospital		
B12 WO 96/14081	5/17/96	Boehringer Manheim gmbh		
B13 WO 02/10743	2/07/02	Ortho McNeil Pharmaceutical, Inc.		

FILING DATE

# NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAP/TAL LETTERS), Title Date, Pertinent Pages, Etc.)	Т
	C04	ALAFACI et al., 2000, "Effect of Recombinant Human Ery propoietin on Cerebral Ischemia Following Experimental Subarachnoid Hymorrhage," Eur. J. Phar., 406:219-225.	
	C02	ANAGNOSTOU et al., 1994 "Erythropoietin receptor mRNA expression in human endothelial cells", Proc. Natl. Acad. Sci. USA 91:3714-3978	
	C04	ANNABLE et al., 1972, The Second International Reference Preparation of Erythropoietin, Human, Urinary, for Bioassay," Bull. Ogc. mond. Sante, 47:99-112.	
	C04	ASHWELL et al., 19/8, "A Protein from Mammalian Liver that Specifically Binds Galactose-Terminated Glycoproteins," Math. Enzymol., 50:287-291.	
	C05	BAUER, 1995, "The Oxygen Sensor That Controls EPO Production: Facts and Fancies," J. Perinat. Med., 23:7-12.	
	C06	BENYO et al., 1999, "Expression of crythropoietin receptor by trophoblast cells in the human placenta", Biol. Reproduct 60:861-870	
	C07	BERNA/DIN et al., 1999, "A potential role for erythropoietin in focal permanent carebral ischemia in mice", J. Cereb Blood Flow Metab. 19:643-651	Γ
	C08	BER/AUDIN et al., 2000, "Neurons and astrocytes express EPO mRNA: oxygen-sensing mechanisms that involve the redox-state of the brain", Glia 30:271-278	
	C09	DONDY, 1995, "The relaxation of oxidative stress and hyperexcitation to neurological disease", Proc. Soc. Exp. Biol. Med. 208:337-345	

EXAMINER NYI-3977311v2

<sup>\*</sup>EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 164 Express Mail No.: DRAFT Sheet 3 of 7 of List of References

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### LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

# NON PATENT LITERATURE DOCUMENTS

FILING DATE

January 3, 2005

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	Т
Initials	C10	BRIGGS et al., 1974, "Hepatic Clearance of Intact and Desialylated Erythropoletin," Am. J. Physiol., 227:1385-1388.	ŕ
	CII	BRINES et al., 2000, "Erythropoietin crosses the blood-brain barrier to protect against experimental brain injury", Proc. Natl. Akad. Sci. USA 97:10526-10531	
	C12	BRUNEVAL et al., 1993, "Erythropoletin Synthesis by Tumor Cells in a Case of Meningioma Associated With Erythrocytosis," Blood, 8 (1593-1597.	
	C13	CAMISCOLI et al., 1968, "Comparative Assay of Erythropoietip Standards," Annals New York Acad. Sci., 149:40-45.	
	CI4	CAMPANA et al., 1998, "Identification of a neurotrophic sequence in erythropoietin", Int. J. Mol. Med. 1:235-241	
	C15	CLAUS-WALKER et al., 1984, "Spinal Cord Injury and Serum Erythropoietin," Arch. Phys. Med. Rehabil., 65:370-374.	
	C16	COTES, 1968, "Quantitative Estimation of Erythropoletin," Part I. Assay and Standardization of Erythropoletin, Annals New York Acad. Sci., 149 2-17.	
	C17	COTES et al., 1961, "Bio-Assay of Erythropoletin in Mice Made Polycythaemic By Exposure to Air at a Reduced Pressure," Nature, 191:1065-1067.	Γ
	C18	COTES et al., 1966, "The International Reference Preparation of Erythropoietin," Bull. Org. mond. Sante, 35:751-760.	
	C19	DIAZ-BRINTON et al., 1998, "Advances and challenges in the prevention and treatment of Alzheimer's disease," Pharm. Res. 15(3):386-98	
	C20	DIGICAYLIOGLU et al. 1995, "Lo-dization of specific erythropoietin binding sites in defined areas of the mouse brain.", Proc. Natl. Acad. Sci. USA 92:3717-3720	
	C24	DIPAOLO et al., 1992, "Effects of uremia and dialysis on brain electrophysiology after recombinant erythropoietin treatment", AS&IO J. 38:M477-M480	
	C22	DONG et al., 1992, "Receptor binding of asialoerythropoietin," Cell. Biochem. 48(3):269-76	
	C23	DORDAL et al., 1985, "The Role of Carbohydrate in Erythropoietin Action," Endocrinol., 116:2293-2299.	T
	C24	DUBE et al, 1988, "Gl-cosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," J. Biol. Chem., 263:17516-17521.	T
	C25	EHRENREICH et al., 2002, "Erythropoietin therapy for acute stroke is both safe and beneficial", Molec. Med. 8(8):495-505	
	C26	Eur. Pharmacopoeia, 1997, p. 5.	T
	C27	Eur. Pharmscopoeia, Suppl. 2001, pp. 777-782.	
	C28	FARREI/L et al., 2001, "Erythropoietin crosses the blood brain barrier", Blood 98:148b (abstr. # 4265; 43rd Annual Meeting of the American Society of Hematology, Orlando FL, Dec. 7-11, 2001)	T
	C29	FEIGIN et al., 2002, "Recent advances in Huntington's disease: implications for experimental therapeutics," Curr. Opin. Neurol. 15(4):483-9	
	C30	PUKUDA et al., 1989, "Survival of Recombinant Erythropoietin in the Circulation: The Role of Carbohydrates," Blood, 73:84-89.	
	C3y	GARTHOFF, 1995, "Safety and Efficacy Testing of Hormones and Related Products," The Report and	

EXAMINER
NYI-3972311v2

<sup>\*</sup>FAAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and a shade copy of this form with next communication to applicant.

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 4 of 7 of List of References

ATTY. DOCKET NO.

APPLICATION NO. 10/520,140 (National Stage of PCT/US20)5/021350)

APPLICANT (Use several sheets if necessary)

APPLICANT
Brines et al.

FILING DATE January 3, 2005 1647

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	Т
		Recommendations of ECVAM Workshop 9, A.T.L.A., 23:699-711	Ė
	C32	GOLDWASSER et al., 1974, "On the Mechanism of Erythropoietin-Induced Differentiation," XIII. The Role of Sialic Acid in Erythropoietin Action, J. Biol. Chem., 249:4202-4206.	
	C33	GOLDWASSER et al., 1975, "An Assay for Erythropoietin in Vitro at the Milliunit Level," Endo., 97:315-323.	Г
	C34	GOLDWASSER et al., "Dythropoietin: Assay and Study of Its Mode of Action," Hormone Assays, pp. 109- 121.	
	C35	GORIO et al., 2002. "Recombinant human erythropoietin countriacts secondary injury and markedly enhances neurological recovery from experimental spinal cord trauma" "roc. Natl. Acad. Sci. USA 99:9450-9455 (PNAS Early Edition www.pnas.org/cgi/doi/10.1073/pnas.1422878/9)	
	C39	GRASSO et al., 2002, "Beneficial effects of systemic administration of recombinant human erythrpoietin in rabbits subjected to subarachnoid hemorrhage", Proc. Natl. Acad. Sci. USA 99:5627-5631	
	C39	GREGORY et al., 1999, "GATA-1 and arythropoietin cooperate to promote erythroid cell survival by regulating bcl-xL expression", Blood 94:87-96	
	C39	GRIMM et al., 1990, "Improvement of brain function in hemodialysis patients treated with erythropoietin", Kidney Intl. 38:480-486	
	C39	HAMMOND et al., 1968, "Production, Utilization and Excretion of Erythropoietin: I. Chronic Anemias. II. Aplastic Crisis. III. Erythropoietic Effects of Normal Plasma," Erythropoietin, 149:516-527.	
	C40	HEFTI, 1997, "Pharmacology of neurotrophic factor", Annu. Rev. Pharmacol. Toxicol. 37:239-267	
	C44	HENGEMIHLE et al., 1996, "Chronio treatment with human recombinant erythropoietin increases hematocrit and improves water maze performance in mice", Physiol. Behav. 59:153-156	
	C42	HIRAKATA et al., 1992, "CBF and oxygen metabolism in remodialysis patients: effects of anemia correction with recombinant human EPO" Am. J. Physiol, 262:F737-F743	
	C44	HORTON et al., 1991, "Von hippel-Lindau Disease and Erythrocytosis: Radioimmunoassay of Erythropoietin in Cyst Fluid From a Brains em Hemangioblastoma," Neurology, 41:753-754.	
	C44	IMAI et al., 1990, "Physic ochemical and Biological Characterization of Asialoerythropoietin," Eur. J. Biochem., 194:457-462.	Г
	C45	JOOSS et al., 1996, "Lyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung," Hum. Gene Ther. 7(13):1555-66	Г
	C46	JUNK et al., 2007, "Erythropoietin administration protects retinal neurons from acute ischemia-reperfusion injury", Proc. Natl. Acad. Sci. As 99:10659-10664 (PNAS Early Edition www.pnas.ox/egi/doi/10.73/pnas.152321399)	
	C47	JUUL et al. 1998, "Erythropoietin and erythropoietin receptor in the developing human central nervous system", ediatr. Res. 43:40-49	
	C48	JUUL of al., 1998, "Tissue distribution of erythropoietin and erythropoietin receptor in the developing human fetus." Early Human Devel, 52:235-249	Г
	C49	JUPL et al., 2001, "Recombinant crythropoietin (EPO) crosses the blood brain barrier (BBB) in preterm fetal sleep", Soc. for Neuroscience Abstracts 27:929 (31st Annual Meeting of the Society for Neuroscience, San Diego, CA Nov. 10-15, 2001)	
	C59	KEIGHLEY, 1968, "Further Experiences with Assays, Units, and Standards of Erythropoietin," Annals New York Acad. Sci., 149:18-24.	Г

	NYI-3972311v2	DATE CONSIDERED	\
-	and the second s		

\*XAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 16/ Express Mail No.: DRAF! Sheet 5 of 7 of List of References

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

AFTY. DOCKET NO. INFRICATION NO. 10/520,140
(National Stage of PCT/US2/03/021350)

APPLICANT
Brines et al.

FILING DATE
January 3, 2005

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#### NON PATENT LITERATURE DOCUMENTS

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Τ	(Include the Control of Capital Leggers) and the Control of Capital Leggers	Т
initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages (Etc.)	Ц.
	C51	KOHAMA et al., 2000, "Large Uterine Myoma with Erythropoietin Messenger RNA and Erythrocytosis,"  Obstetrics and Goecology, 96:826-828.	
	C52	KONISHI et al., 1933, "Trophic effect of erythropoietin and other hematopoietic factors on central cholinergic	
	032	neurons in vitro and it vivo", Brain Res. 609:29-35	
	C53	KOPF et al., 1994, "Memory improving actions of glucose: involvement of a central cholinergic muscarinic mechanism.", Behav. Neural Biol. 62:237-243	
	C54	LATINI et al., 1998, "Comparative efficacy of a DA2/α2 agonist and a β blocker in reducing adrenergic drive	
	100.	and cardiac fibrosis in an experimental model of left ventricular dysfunction after coronary artery occlusion", J.	
		Cardiovasc. Pharmacol. 31:601 608	
	C58	LI et al., 1996, "Erythropoietin receptors are expressed in the central nervous system of mid-trimester human	
		fetuses", Pediatr. Res. 40:376-380	
	C58	LI et al., 1998, "A single pre training Aucose injection induces memory facilitation in rodents performing	
		various tasks: contribution of acidic fibr blast growth factor", Neurosci. 85:785-794	
	C57	LIPINSKI et al., 1995, "Nerve growth factor facilitates conditioned taste aversion learning in normal rats", Brain	
		Res. 692:143-153	
	C58	LIU et al., 1996, "Transgenic mice containing the human crythropoietin receptor gene exhibit correct	
		hematopoietic and neural expression", Proc. Ass. C. Am. Physicians 108:449-454	
	C58	LIU et al., 1997, "Regulated human erythropoietin receptor expression in mouse brain", J. Biol. Chem. 272:32395-32400	
	C60	LIU et al., 1994, "Tissue specific expression of human crythropoietin receptor in transgenic mice", Devel. Biol. 166:159-169	
	C61	LOWY et al., 1960, "Inactivation of Erythropoietin by Nearaminidase and by Mild Substitution Reactions," Nature, 185:102-103.	
	C62	MARRERO et al., 1998, "Eryphropoietin receptor-operated Cas+ channels: activation by phospholipase C-γ1",	
		Kidney Intl. 53:1259-1268	
	C63	MARSH et al., 1991, "rHy PO treatment improves brain and cognitive function of anemic dialysis patients", Kidney Intl. 39:155-163	
	C64	MARTI et al., 1997, "Setection of erythropoietin in human liquor: introsic crythropoietin production in the brain", Kidney Intl. 7:416-418	
	C65	MARTI et al., 1996, "Erythropoietin gene expression in human, monkey and murine brain", Eur. J. Neurosci.	$\vdash$
		8:666-676	
	C66	MASUDA et 31., 1997, "Insulin like growth factors and insulin stimulate erythropoietin production in primary cultured astrocytes", Brain Res. 746:63-70	
	C67	MASUDA et al., 1994, "A novel site of erythropoietin production. Oxygen dependant production in cultured rat astrocytes", J. Biol. Chem. 269:19488-19493	
	C68	MASUDA et al., 1993, "Functional erythropoietin receptor of the cells with neural characteristics. Comparison with receptor properties of erythroid cells", J. Biol. Chem. 268:11208-11216	
<b> </b>	<del></del>	MATSUYAMA et al., 2000, "Erythrocytosis Caused by an Erythropoietin-Producing Hepatocellular	-
	C69	Carcinoma," J. Surg. Oncology, 75:197-202.	
	-	MIONI et al., 1992, "Evidence for specific binding and stimulatory effects of recombinant human erythropoietin	-
	C70	on isolated adult rat Leydig cells", Acta Endocrinologica 127:459-465	
	/	on isolated addit fat Leydig cens , Acta Endocrinologica 127:459-465	Ь.

MINER 1972311v2	DATE CONSIDERED

<sup>\*</sup>EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and a considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 1647 Express Mail No.: DRAFT

Sheet 6 of 7 of List of References

ATTY. DOCKET NO. APPLICATION NO. 10/520,140 (National Stage of PCT/US2002/021350) 10165-037-999 LIST OF REFERENCES CITED BY APPLICANT APPLICANT (Use several sheets if necessary) Brines et al. FILING DATE January 3, 2005

# NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	т
imitiais	C71	MIYAKE et al., 1977, "Purification of Human Erythropoietin," J. Biol. Chem. 252:5558-5564.	
		MORELL et al., 1968, "Physical and Chemical Studies on Ceruloplasmin," Metabolic Studies on Sialic Acid-	
	C72	Free Ceruloplasmin In Vivo, J. Biol. Chem., 243:155-159.	
	C73	MORISHITA et al., 1997, "Erythropoietin receptor is expressed in rat hippocampal and cerebral cortical	
	10.0	neurons, and erythropoieth prevents in vitro glutamate induced neuronal death", Neurosci. 76:105-116	
	C74	MOSS et al., 1996, "Oxygen administration enhances memory formation in healthy young adults",	
	_	Psychopharmacol. 124:255-260	_
	C75	NAKAMURA et al., 1998, "Elevated levels of erythropoietin in cerebrospinal fluid of depressed patients", Am. J. Med. Sci. 315:199-201	
	C79	NISSENSON et al., 1991, "Recombigant human crythropoietin and renal anemia; molecular biology, clinical	
	C/9	efficacy and nervous system effects", Ann. Int. Med. 114/102-416	
	C79	NISSENSON, 1989, "Recombinant human erythropoieth: impact on brain and cognitive function, exercise	
		tolerance, sexual potency and quality of lile,", Sem. Nephrol. 9(suppl. 2):25-31	
	C78	OGDEN, 1989, "Monitoring considerations to recombinant human erythropoietin therapy", Sem. Nephrol.	
		9(suppl. 2):12-15	
	C79	OKADA et al., 1996, "Erythropoietin stimulates proliferation of rat-cultured gastric mucosal cells", Digestion 57:328-332	
	C80	PARDRIDGE, 1997, "Drug delivery to the brain", J. Cerebral Blood Flow Metab. 17:713-731	
	C84	PARDRIDGE et al., 1991, "Selective transport of an anti-transferrin receptor antibody through the blood-brain	$\vdash$
	1004	barrier in vivo", J. Pharmacol. Exp. Tyer. 27:66-70	
	C82	PLAPP et al., 1971, "Activity of boyine pancreatic deoxyribenuclease A with modified amino groups," J. Biol.	
		Chem. 246(4):939-45	
	C84	PODUSLO et al., 1994, "Macromolecular premeability across the blood-nerve and blood-brain barriers", Proc.	
		Natl. Acad. Sci. USA 91:5709-5709	_
	C84	PRENDERGAST et al., 1997, "Nitric oxide synthase inhibition impairs spatial navigation learning and induces conditioned taste aversion", Pharmacol. Biochem. Behav. 57:347-352	
	C85	ROBINSON et al., 1978, "Tetanus toxin. The effect of chemical modifications on toxicity, immunogenicity, and	$\vdash$
	C85	conformation," J. Biol. Chem. 250(18):7435-42	
	C79	ROSE et al., 1998 Receptor-mediated angiotensin II transcytosis by brain nicrovessel endothelial cells",	1
		Peptides 19:1023 1030	
	C87	SADAMATO et al., 1998, "Erythropoietin prevents place navigation disability and cortical infarction in rats	
		with permanent occlusion of the middle cerebral artery", Biochem. Biophys. Res. Comm. 253:26-32	
	C88	SAKANAKA et al., 1998, "In vivo evidence that erythropoietin protects neurons from ischemic damage", Proc. Natl. Ac.d. Sci. USA 95:4635-4640	
	C89	SATAKE et al. 1990, "Chemical modification of erythropoietin: an increase in in vitro activity by	i—
	C89	guardination," Biochim. Biophys. Acta. 1038(1):125-9	
	C90	SAWYER et al., 1989, "Receptors for erythropoietin in mouse and human erythroid cells and placenta", Blood	†
	570	4:103-109	
	C91	SHIRAMIZU et al., 1994, "Constitutive Secretion of Erythropoietin by Human Renal Adenocarc noma Cells in	
	/	Vivo and in Vitro," Exp. Cell Res., 215:249-256.	

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EXAMINER
NY1-3972311v2

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 7 of 7 of List of References

ATTY. DOCKET NO. APPLICATION NO 10/520,140 (National Stap of 10165-037-999 PCT/US2009/021350)
APPLICANT Brines et al.

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# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

# NON PATENT LITERATURE DOCUMENTS

FILING DATE

January 3, 2005

Examiner Initials		(In the Control of CARITAL I PERFORM THE DATE OF THE CONTROL OF TH	т
initials	C92	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)  SHORE et al., 1968, "Quantitative Estimation of Erythropoietin," Annals New York Acad. Sci., 149:46-48.	<del>  '-</del>
_	C93	SILVA et al., 1999, "Erythropoietin can induce the expression of bcl-xL through Stat5 in erythropoietin- dependent progenitor cell lines", J. Biol, Chem. 274:22165-22169	
	C94	SIRÉN et al., 2001, "En thropoietin prevents neuronal apoptosis after ce ebral ischemia and metabolic stress", Proc. Natl. Acad. Sci. USA 98:4044-4049	
	C95	SPIVAK et al., 1989, "The in Vivo Metabolism of Recombinant Human Erythropoietin in the Rat," Blood, 73:90-99.	
	C96	STARK et al., 1960, "Reactions of the Cyanate Present in Aques us Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-3181	
	C97	STEECE-COLLIER et al., 2002, "Pulology of Parkinson's disease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22):1397-4	
	C98	STORRING et al., 1998, "Epoietin Alfa and Beta Differ in Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100:79-89.	
	C99	STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-drived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," J. Endocrinol., 134:49-484.	
	C100	SUZUKI et al., 2001, "Erythropoietin Synthesis b Tumour Tissues in a Patient With Uterine Myoma and ERythrocytosis," British J. Haematology, 1/3:49-51	
	C101	TABIRA et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons in vitro". Int. J. Devl. Neurosci. 13:241-252	
	C102	WEILAND et al., "In vivo Activity of Asialo-Erythropoteta in Combination with Asialo-Glycoproteins," 1982, Blut. 44:173-175.	
	C103	WESTENFELDER et al., 1999, "fuman, rat and mouse kidne, cells express functional crythropoietin receptors", Kidney Intl. 55:808/820	
	C104	WILLIAMS et al., 1994, "Hyman erythropoietin receptor", Ann. N. Acad. Sci. 718:232-244	
	C105	WOLCOTT et al., 1989, "ecombinant human crythropoietin treatment may improve quality of life and cognitive function in chronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485	
	C106	WU et al., 1999, "Newtoprotection with noninvasive neurotrophin delivery to the brain", PNAS 96:254-259	
	C107	YAMAJI et al., 1996, "Brain capillary endothelial cells express two forms of crythropoietin receptor mRNA", Eur. J. Biochem. 239:494-500	
	C108	YANG et al., 2002, "Effects of ammonia and glucosamine on the heterogeneity of crythropoietin glycoforms," Biotechnol. Prog. 18(1):129-38	

EXAMINER NYI-3972311v2

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 164 Express Mail No.: DRAFT Sheet I of 7 of List of References

ATTY. DOCKET NO.

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APPLICATION NO.

APPLICATION NO.

APPLICATION NO.

APPLICATION NO.

I/0520,140
(National Style of PCT/US29/03/021350)

APPLICANT
Brines et al.

FILING DATE
January 3, 2005

647

#### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVAN FIGURES APPEAR
	A01	4,377,513	03/22/83	Sugimoto et al.	
	A02	4,703,008	10/27/87	Lin	
	A03	4,806,524	02/21/89	Kawaguchi et al.	
	A04	4,835,260	05/30/89	Shoemaker	
	A05	5,457,089	10(10/95	Fibi et al.	
	A06	5,547,933	08/20/96	Lin	
	A07	5,571,787	11/05/90	O'Brien et al.	
	A09	5,614,184	03/25/97	Sytkowski et al	
	A09	5,618,698	04/08/97	in	
	A10	5,621,080	04/15/97	Lin	
	All	5,625,035	04/29/97	Clemos	
	A12	5,661,125	08/26/97	Strickland	
	All	5,696,080	12/09/97	6 Brien	
	AH	5,700,909	12/23/97	O'Brien	
	All	5,714,459	02/03/98	O'Brien	
	Ale	5,756,349	05/26/98	Lin	
	A17	5,767,078	06/16/98	Johnson et al.	
	A18	5,773,569	66/30/98	Wrighton et al.	
	A19	5,830,851	11/03/98	Wrighton et al.	
	A20	5,835,382	11/10/98	Wilson et al.	
	A21	5,856,298	01/05/99	Strickland	
	A22	5,888,772	03/30/99	Okasinski et al.	
	A23	5,955,422	09/21/99	Lin	\
	A24	6,165,785	12/26/00	Weiss et al.	
	A25	4,658,019	04/14/87	Kung et al.	

#### FOREIGN PATENT DOCUMENTS

EXAMILER
NYI-39/2311v2
Date Considered

<sup>\*</sup>pd.AMINER\* Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and no sonsidered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATYY. DOCKET NO.

APPLICATION NO.
10/520,140
(National Stage of
PCT/US2008/021350)

APPLICANT
Brines et al.

FILING DATE
January 3, 2005

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January 3, 2005

	OREIGN PATENT OCCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE ELEVANT PASSAGES OR ELEVANT FIGURES APPEAR	т
B01	JP 5-24688	09/24/93	JP-A Kokai		
B02	WO 94/24160	10/27/94	Brigham and Women's Hospital		
B03	WO 95/05465	02/23/95	Amgen, Inc.		
B04	WO 97/18318	05/22/97	Takara Shuzo Co., Ltd.		
B05	WO 97/32895	12/12/97	Regents of the University of Valifornia		
B06	WO 98/18926	5/07/98	G.D. Searle & Co.		
B07	WO 00/35475	06/82/00	Ehrenreich		
B08	WO 01/82952	11/08/01	Action Pharma APS		
B09	WO 01/82953	11/08/01	Action Pharma APS		
B10	EP 555880	08/18/93	Bristol-Myers Quibb Company		
BII	WO 92/08493	5/29/92	Brigham & Nomen's Hospital		
B12	WO 96/14081	5/17/96	Bothringer Manheim gmbh		
B13	WO 02/10743	2/07/02	Ortho McNeil Pharmaceutical, Inc.		

#### NON PATENT LATERATURE DOCUMENTS Examiner (Include name of the author (in CAPPIAL LETTERS), Title, Nate, Pertinent Pages, Etc.) ALAFACI et al., 2000, "Effect of Recombinant Human Erythopoietin on Cerebral Ischemia Following Experimental Subarachnoid Hymorrhage," Eur. J. Phar., 406-20, 2023. Initials т C01 ANAGNOSTOU et al., 1994 "Erythropoietin receptor mRNA expression in human endothelial cells", Proc. C02 Natl. Acad. Sci. USA 91:3/74-3978 ANNABLE et al., 1972 / The Second International Reference Preparation of Erythropoietin, Human, Urinary, C01 for Bioassay," Bull. Org. mond. Sante, 47:99-112. ASHWELL et al., 1978, "A Protein from Mammalian Liver that Specifically Binds Galactose-Terminated C01 Glycoproteins," Meth. Enzymol., 50:287-291. BAUER, 1995, The Oxygen Sensor That Controls EPO Production: Facts and Fancies," J. Perinat. Med., 23:7-C05 12. BENYO et al., 1999, "Expression of erythropoietin receptor by trophoblast cells at the human placenta", Biol. C06 Reproduct 60:861-870 BERNAUDIN et al., 1999, "A potential role for erythropoietin in focal permanent celebral ischemia in mice", J. C07 Cereb Blood Flow Metab. 19:643-651 NAUDIN et al., 2000, "Neurons and astrocytes express EPO mRNA; oxygen-sensing mechanisms that C08 involve the redox-state of the brain", Glia 30:271-278 SONDY. 1995, "The relaxation of oxidative stress and hyperexcitation to neurological disease", Proc. Soc. Exp. C09 Biol. Med. 208:337-345

EXAMINER NYI-39/2311v2

<sup>\*</sup>FAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and onsidered. Include copy of this form with next communication to applicant.

10520140 - GAU: 164 Express Mail No.: DRAFT Sheet 3 of 7 of List of Reference

ATTY. DOCKET NO. 10165-037-999	APPLICATION NO. 10/520,140 (National Stage of PCT/US20/63/021350)
APPLICANT	
Brines et al.	
FILING DATE January 3, 2005	ARTUNIT

# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

# NON PATENT LITERATURE DOCUMENTS

Examiner			_
Initials	+	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Mc.)  BRIGGS et al., 1974, "Hepatic Clearance of Intact and Desialylated Erythropoletin," Am. J. Physiol., 227:1385-	T
	C10	1388.	
	CII	BRINES et al., 2000, "Erythropoietin crosses the blood-brain barrier to protect against experimental brain	$\vdash$
	0	injury", Proc. Natl. Asad. Sci. USA 97:10526-10531	
	C12	BRUNEVAL et al., 1998, "Erythropoietin Synthesis by Tumor Cells in a Case of Meningioma Associated With Erythrocytosis," Blood, 8 1593-1597.	
	CI3	Erythrocytosis," Blood, \$3, 1593-1597.  CAMISCOLI et al., 1968, "Comparative Assay of Erythropoietin standards," Annals New York Acad. Sci., 149:40-45.	
	C14	CAMPANA et al., 1998, "Identification of a neurotrophic section in erythropoietin", Int. J. Mol. Med. 1:235- 241	
	C15	CLAUS-WALKER et al., 1984, "Spinal Cord Injury and Serum Erythropoietin," Arch. Phys. Med. Rehabil., 65:370-374.	
	C16	COTES, 1968, "Quantitative Estimation of Erythropotetin," Part I. Assay and Standardization of Erythropotetin, Annals New York Acad. Sci., 149: 12-17.	
	C17	COTES et al., 1961, "Bio-Assay of Erythropoietis in Mice Made Polycythaemic By Exposure to Air at a Reduced Pressure," Nature, 191:1065-1067.	
	C18	COTES et al., 1966, "The International Reference Preparation of Erythropoietin," Bull. Org. mond. Sante, 35:751-760.	
	C19	DIAZ-BRINTON et al., 1998, "Advance and challenges in the prevention and treatment of Alzheimer's disease," Pharm. Res. 15(3):386-98	
	C20	DIGICAYLIOGLU et al. 1995, "Loof lization of specific crythropoietin binding sites in defined areas of the mouse brain.", Proc. Natl. Acad. Sp. USA 92:3717-3720	
	C21	DIPAOLO et al., 1992, "Effects of uremia and dialysis on bruin electrophysiology after recombinant erythropoletin treatment", ASAO J. 38:M477-M480	П
	C22	DONG et al., 1992, "Receptor binding of asialoerythropoietin," Cell. Biochem. 48(3):269-76	$\overline{}$
	C23	DORDAL et al., 1985, "The Role of Carbohydrate in Erythropoietil Action," Endocrinol., 116:2293-2299.	
	C21	DUBE et al, 1988, "Giz cosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," J. Biol. Chem., 263:17516-17521.	
	C25	EHRENREICH et al., 2002, "Erythropoietin therapy for acute stroke is both safe and beneficial", Molec. Med. 8(8):495-505	
	C26	Eur. Pharmacopoeia, 1997, p. 5.	
	C27	Eur. Pharmscopoeia, Suppl. 2001, pp. 777-782.	
	C28	FARRELL et al., 2001, "Erythropoietin crosses the blood brain barrier", Blood 98: 1886 (abstr. # 4265; 43rd Annual Meeting of the American Society of Hematology, Orlando FL, Dec. 7-11, 200)	
	C29	FEIO(N et al., 2002, "Recent advances in Huntington's disease: implications for experimental therapeutics," Curr. Opin. Neurol. 15(4):483-9	
	C30	JUKUDA et al., 1989, "Survival of Recombinant Erythropoietin in the Circulation: The Role of Carbohydrates," Blood, 73:84-89.	
	C31	GARTHOFF, 1995, "Safety and Efficacy Testing of Hormones and Related Products," The Report and	

MUNER 9/2311v2	DATE CONSIDERED

<sup>\*</sup>FAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and onsidered. Include copy of this form with next communication to applicant.

10520140 - GAU: 164 Express Mail No.: DRAFT Sheet 4 of 7 of List of References

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ATTY. DOCKET NO.	APPLICATION NO. 10/520,140 (National State of
10165-037-999	PCT/US20/3/021350)
APPLICANT	
Brines et al.	
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January 3, 2005	1647

# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

# NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Pic.)	т
- Initialis		Recommendations of ECVAM Workshop 9, A.T.L.A., 23:699-711	Ė
	C32	GOLDWASSER et al., 1974, "On the Mechanism of Erythropoietin-Induced Differentiation," XIII. The Role of Sialic Acid in Erythropoietin Action, J. Biol. Chem., 249:4202-4206.	
	C33	GOLDWASSER et al. 1975, "An Assay for Erythropoietin in Vitro at the Milliunit Level," Endo., 97:315-323.	
	C34	GOLDWASSER et al., "Trythropoletin: Assay and Study of Its Mode of Action," Hormone Assays, pp. 109- 121.	
	C35	GORIO et al., 2002, "Recombinant human erythropoietin countracts secondary injury and markedly enhances neurological recovery from experimental spinal cord trauma" roc. Natl. Acad. Sci. USA 99.9450-9455 (PNAS Early Edition www.pnas.org/egi/doi/10.1073/pnas.14228789)	
	C38	GRASSO et al., 2002, "Beneficial effects of systemic administration of recombinant human erythrpoietin in rabbits subjected to subarachnoid hemorrhage", Proc. Nail. Acad. Sci. USA 99:5627-5631	
	C37	GREGORY et al., 1999, "GATA-1 and crythropoietin cooperate to promote erythroid cell survival by regulating bcl-xL expression", Blood 94:87-96	
	C38	GRIMM et al., 1990, "Improvement of brain function in hemodialysis patients treated with erythropoietin", Kidney Intl. 38:480-486	
	C38	HAMMOND et al., 1968, "Production, Utilization and Excretion of Erythropoietin: J. Chronic Anemias. II.  Aplastic Crisis. III. Erythropoietic Effects of Normal Plasma," Erythropoietin, 149:516-527.	
	C40	HEFTI, 1997, "Pharmacology of neurotrophic factors", Annu. Rev. Pharmacol. Toxicol. 37:239-267	
	C41	HENGEMIHLE et al., 1996, "Chronic freatment with human recombinant erythropoietin increases hematocrit and improves water maze performance in mice", Physiol Behav. 59:153-156	
	C42	HIRAKATA et al., 1992, "CBF and oxygen metabolism in themodialysis patients: effects of anemia correction with recombinant human EPO", Am. J. Physiol. 262:F737-F 43	
	C43	HORTON et al., 1991, "Von Hippel-Lindau Disease and Erythrocytosis: Radioimmunoassay of Erythropoietin in Cyst Fluid From a Brainstein Hemangioblastoma," Neurology 41:753-754.	
	C44	IMAI et al., 1990, "Physic chemical and Biological Characterization of Asialoerythropoietin," Eur. J. Biochem., 194:457-462.	
	C45	JOOSS et al., 1996, "Cyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung," Hum. Gene Ther. 7(13):1555-66	
	C46	JUNK et al., 2002 Erythropoietin administration protects retinal neurons from acute ischemia-reperfusion injury", Proc. Nyfl. Acad. Sci. USA 99:10659-10664 (PNAS Early Edition www.pnas.org/cgi/doi/10.1073/pnas.152321399)	
	C47	JUUL et al., 1998, "Erythropoietin and erythropoietin receptor in the developing ruman central nervous system", Bediatr. Res. 43:40-49	
	C48	JUUL et al., 1998, "Tissue distribution of erythropoietin and erythropoietin receptor in the developing human fetus" Early Human Devel. 52:235-249	
	C49	JUJC et al., 2001, "Recombinant erythropoietin (EPO) crosses the blood brain barrier (BAB) in preterm fetal style,", Soc. for Neuroscience Abstracts 27-929 (31st Annual Meeting of the Society for Neuroscience, San Mego, CA Nov. 10-15, 2001)	
	C50	KEIGHLEY, 1968, "Further Experiences with Assays, Units, and Standards of Erythropoietin, Annals New York Acad. Sci., 149:18-24.	

EXAMINER.
NYI-3922311v2

<sup>\*</sup>ELAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 1647 Express Mail No.: DRAFT Sheet 5 of 7 of List of Reference

1647

ATTY. DOCKET NO.

APPLICATION NO.
10/520,140
(National Stage of PCT/US2003/021350)

APPLICANT
Brines et al.

FILING DATE

ARXUNIT

January 3, 2005

# LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

#### NON PATENT LITERATURE DOCUMENTS

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Ptc.)	Т
imuais	C51	KOHAMA et al. 2000, "Large Uterine Myoma with Erythropoietin Messenger RNA and Erythrocytosis,"  Obstetrics and Graceology, 96:826-828.	·
	C52	KONISHI et al., 1993, "Trophic effect of erythropoietin and other hematopoietic factors on central cholinergic neurons in vitro and it vivo", Brain Res. 609:29-35	
	C53	KOPF et al., 1994, "Memory improving actions of glucose: involvement of a central cholinergic muscarinic mechanism.", Behav. Neoral Biol. 62:237-243	
	C54	LATINI et al., 1998, "Combarative efficacy of a DA2/α2 agonist and a β blocker in reducing adrenergic drive and cardiac fibrosis in an experimental model of left ventricular dysfunction after coronary artery occlusion", J. Cardiovase, Pharmacol. 31.50 № 08	
	C56	LI et al., 1996, "Erythropoietin receptors are expressed in the central nervous system of mid-trimester human fetuses", Pediatr. Res. 40:376-380	
	C56	LI et al., 1998, "A single pre training alucose injection induces memory facilitation in rodents performing various tasks: contribution of acidic fibroblast growth factor", Neurosci. 85:785-794	
	C57	LIPINSKI et al., 1995, "Nerve growth factor facilitates conditioned taste aversion learning in normal rats", Brain Res. 692:143-153	
	C57	LIU et al., 1996, "Transgenic mice containing the human erythropoietin receptor gene exhibit correct hematopoietic and neural expression", Proc. 453 oc. Am. Physicians 108:449-454	
	C56	LIU et al., 1997, "Regulated human erythropoietik receptor expression in mouse brain", J. Biol. Chem. 272:32395-32400	
	C60	LIU et al., 1994, "Tissue specific expression of human crythropoietin receptor in transgenic mice", Devel. Biol. 166:159-169	
	C61	LOWY et al., 1960, "Inactivation of Erythropoietin by Neuraminidase and by Mild Substitution Reactions," Nature, 185:102-103.	Т
	C62	MARRERO et al., 1998, "Erytyropoietin receptor-operated Ca2+ channels: activation by phospholipase C-y1", Kidney Intl. 53:1259-1268	
	C63	MARSH et al., 1991, "rHutPO treatment improves brain and cognitive function of anemic dialysis patients", Kidney Intl. 39:155-163	
	C64	MARTI et al., 1997, "Detection of erythropoietin in human liquor: inflinsic erythropoietin production in the brain", Kidney Intl. 5:416-418	Г
	C65	MARTI et al., 1996, "Erythropoietin gene expression in human, monkey and murine brain", Eur. J. Neurosci. 8:666-676	Г
	C66	MASUDA et al., 1997, "Insulin like growth factors and insulin stimulate crythropoietin production in primary cultured astrocytes", Brain Res. 746:63-70	
	C67	MASUDA et al., 1994, "A novel site of erythropoietin production. Oxygen dependent production in cultured rat astrocyter", J. Biol. Chem. 269:19488-19493	
	C68	MASUOA et al., 1993, "Functional erythropoietin receptor of the cells with neural characteristics. Comparison with receptor properties of erythroid cells", J. Biol. Chem. 268:11208-11216	П
	C69	Ma TSUYAMA et al., 2000, "Erythrocytosis Caused by an Erythropoietin-Producing Hepatocellular Carcinoma," J. Surg. Oncology, 75:197-202.	
	C70	MIONI et al., 1992, "Evidence for specific binding and stimulatory effects of recombinant human erythropoietin on isolated adult rat Leydig cells", Acta Endocrinologica 127:459-465	
		1	

EXAMINER.
NYI-3972311v2

<sup>\*</sup>E/AMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

10520140 - GAU: 167 Express Mail No.: DRAF Sheet 6 of 7 of List of References

ATTY. DOCKET NO. APPLICATION NO. 10/520, 140 (National Stage of PCT/US2003/021350)

APPLICANT Brines et al.

FILING DATE January 3, 2005

#### NON PATENT LITERATURE DOCUMENTS

		TOTAL BILLIAN BOOK MENTO	
Examiner Initials		(Include name of the author (in CAPITAL LETTERS). Title, Date, Pertinent Pages Etc.)	т
minus	C71	MIYAKE et al., 977, "Purification of Human Erythropoietin," J. Biol. Chept., 252:5558-5564.	<u> </u>
	C72	MORELL et al., 1968, "Physical and Chemical Studies on Ceruloplasmin," Metabolic Studies on Sialic Acid- Free Ceruloplasmin & Vivo, J. Biol. Chem., 243:155-159.	
	C73	MORISHITA et al., 1997, "Erythropoietin receptor is expressed in ray hippocampal and cerebral cortical neurons, and erythropoietin prevents in vitro glutamate induced neuronal death", Neurosci. 76:105-116	
	C74	MOSS et al., 1996, "Oxygen administration enhances memory formation in healthy young adults", Psychopharmacol. 124:255-240	
	C75	NAKAMURA et al., 1998, "Elevated levels of erythropoietin in cerebrospinal fluid of depressed patients", Am. J. Med. Sci. 315:199-201	
	C76	NISSENSON et al., 1991, "Recombinant human erythropoietin and renal anemia: molecular biology, clinical efficacy and nervous system effects". Ann. Int. Med. 114:402-416	
	C76	NISSENSON, 1989, "Recombinant human erythropoletin: impact on brain and cognitive function, exercise tolerance, sexual potency and quality of he.", Sem. Nephrol. 9(suppl. 2):25-31	
	C76	OGDEN, 1989, "Monitoring considerations in recombinant human erythropoietin therapy", Sem. Nephrol. 9(suppl. 2):12-15	
	C76	OKADA et al., 1996, "Erythropoietin stimulates proliferation of rat-cultured gastric mucosal cells", Digestion 57:328-332	
	C80	PARDRIDGE, 1997, "Drug delivery to the brain", Cerebral Blood Flow Metab. 17:713-731	
	C81	PARDRIDGE et al., 1991, "Selective transport of an ani-transferrin receptor antibody through the blood-brain barrier in vivo", J. Pharmacol. Exp. Ther. 27:66-70	
	C82	PLAPP et al., 1971, "Activity of bovine pancreatic deoxyri conuclease A with modified amino groups," J. Biol. Chem. 246(4):939-45	
	C81	PODUSLO et al., 1994, "Macomolecular premeability across the blood-nerve and blood-brain barriers", Proc. Natl. Acad. Sci. USA 91:5795-5709	
	C84	PRENDERGAST et al., 1997, "Nitric oxide synthase inhibition impairs spatial navigation learning and induces conditioned taste aversion", Pharmacol. Biochem. Behav. 57:347-35	
	C85	ROBINSON et al., 1975, "Tetanus toxin. The effect of chemical modifications on toxicity, immunogenicity, and conformation," J. Bjól. Chem. 250(18):7435-42	
	C85	ROSE et al., 1998 "Receptor-mediated angiotensin II transcytosis by brain microvessel endothelial cells", Peptides 19:102-1030	
	C87	SADAMATOet al., 1998, "Erythropoietin prevents place navigation disability and cortical infarction in rats with permanent occlusion of the middle cerebral artery", Biochem. Biophys. Res. Comm. 253:26-32	Г
	C88	SAKANAKA et al., 1998, "In vivo evidence that erythropoietin protects neurons from ischemic damage", Proc. Natl. Acid. Sci. USA 95:4635-4640	
	C89	SATAKE et al. 1990, "Chemical modification of erythropoietin: an increase in in vitro activity by guardination," Biochim. Biophys. Acta. 1038(1):125-9	
	C90	Sa/WYER et al., 1989, "Receptors for erythropoietin in mouse and human erythroid cells and placenta", Blood 14:103-109	
	C91	SHIRAMIZU et al., 1994, "Constitutive Secretion of Erythropoietin by Human Renal Adenocacinoma Cells in Vivo and in Vitro," Exp. Cell Res., 215:249-256.	

EXAM <b>U</b> NER	
NYI-39/2311v2	

10520140 - GAU: 164 Express Mail No.: DRAFT

ATTY DOCKET NO. APPLICATION NO 10/520,140 (National State of 10165-037-999 PCT/US2003/021350)

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

APPLICANT
Brines et al.

FILING DATE ARYUNIT
January 3, 2005 647

#### NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T		
	C92	SHORE et al., 1968, "Quantitative Estimation of Erythropoietin," Annals New York Acad. Sci., 149:46-48.	Ť		
	C93	SILVA et al., 1999, "Erythropoietin can induce the expression of bcl-xL through Stat5 in erythropoietin- dependent progenitor cell lines", J. Biol. Chem. 274:22165-22169	Т		
	C94	SIRÉN et al., 2001, "Brythropoietin prevents neuronal apoptosis after perebral ischemia and metabolic stress", Proc. Natl. Acad. Sci. USA 98:4044-4049			
	C95	SPIVAK et al., 1989, "The In Vivo Metabolism of Recombinant Human Erythropoietin in the Rat," Blood, 73:90-99.			
	C96	STARK et al., 1960, "Reactions of the Cyanate Present in Aqueous Urea With Amino Acids and Proteins," J. Biol. Chem. 235(11): 3177-318			
	C97	STEECE-COLLIER et al., 2002, "Ctiology of Parkinson's insease: Genetics and environment revisited," Proc. Natl. Acad. Sci. U. S. A. 99(22):139 2-4			
	C98	STORRING et al., 1998, "Epoietin Afra and Beta Diffe In Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100 79-89.			
	C99	STORRING et al., 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant Di Agentived Erythropoietins and Two Highly Purified Human Urinary Erythropietins," J. Endocrinol., 134,29-484.			
	C100				
	C101	vitro", Int. J. Devl. Neurosci. 13:241-262			
	C102	WEILAND et al., "In vivo Activity Asialo-Erythropoletin in Combination with Asialo-Glycoproteins," 1982, Blut, 44:173-175.			
	C103	WESTENFELDER et al., 1999 Human, rat and mouse kidney cells express functional erythropoietin receptors", Kidney Intl. 55:809-820			
	C104	WILLIAMS et al., 1994, "Haman erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244	$\top$		
	C105	WOLCOTT et al., 1989. Recombinant human erythropoietin treatment may improve quality of life and cognitive function in chronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485			
	C106	WU et al., 1999, "Nearoprotection with noninvasive neurotrophin delivery to the brain", PNAS 96:254-259	T		
	C107	YAMAJI et al., 1966, "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA", Eur. J. Biochem 239:494-500			
	C108	YANG et al., 7002, "Effects of ammonia and glucosamine on the heterogeneit of erythropoietin glycoforms," Biotechnol. rog. 18(1):129-38			

	-
E	XAMINER
l N	YI-397 311v2

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.